SELF SURVEY MODULE
PRIVACY AND CONFIDENTIALITY OF THE RESIDENT
TAG F164

REGULATION:
F164 (e) Privacy and Confidentiality
The resident has the right to personal privacy and confidentiality of his or her personal clinical records.
(1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide private room for each resident;
(2) Except as provided in paragraph (e) (3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;
(3) The resident's right to refuse release of personal and clinical records does not apply when --
(i) The resident is transferred to another health care institution;
or
(ii) Record release is required by law.
INTENT:
The intent of this regulation is to assure that the privacy and confidentiality of the resident is not compromised. Facility staff must ensure that their actions maintain the rights of privacy and confidentiality for the resident.
DATA COLLECTION:
OBSERVATIONS:
A. Tour the facility and look and listen carefully for any denial of privacy and confidentiality of residents. If you observe any violations of residents' privacy, interview the resident and/or their representative to determine the resident's feelings regarding the incident. Always note the following:
1. **How** did you observe this?
2. **Where** is this taking place? (room number or location)
3. **When** did you observe this? (date and time)
4. **What** has you concerned?
Write down any observations that do not reflect privacy or confidentiality for residents after you do your tour.
B. During the tour, think of the following questions:
1. Are staff knocking on doors and waiting to be asked in?
2. When you knock and are invited in:
a. Are residents covered/dressing?
b. Are privacy curtains used?

c. Are curtains/blinds drawn during personal care (such as bed baths, incontinence care, etc.)?
d. Who is in the room? Explain why they are there.
3. Are residents properly covered during transport to shower/bath?

4. Is privacy provided for physician visit or rehabilitation service?
5. Is there privacy when toileting (in bathroom, on bedside commode, on bed pan or urinal)?
6. Is bathroom door closed when bathroom is in use?
7. Is there a telephone available for private conversations?
8. Do residents receive and send their mail unopened?
9. During observations can staff be overheard discussing confidential resident information?
10. Are all records pertaining to residents in an area that ensures privacy?
11. Are policies and procedures for the release of residents' records being used (i.e., signatures for permission from the resident or their representative?)

C. Begin the second part of the survey looking at those areas of concern you noted, as well as all aspects of privacy and confidentiality. Use the supplied questions as you do the following:

1. Look carefully (observation)
2. Interview and ask questions of residents, staff, and family members.
3. Review the records (i.e., if resident keeps unclothing themselves or is toileting publicly).

*** Respond to concerns by developing and implementing a plan of action. Repeat the survey in the future to assure your action plan has been implemented.

INTERVIEWS:

RESIDENT INTERVIEW:

1. Are you satisfied with the way you are dressed or covered around other people?
2. Do Staff keep other residents dressed or covered?
3. When you need medical treatment or hygiene assistance, is anyone other than the doctor, nurse, or staff person assisting you allowed to be in the room?
4. During rehabilitation therapies, do staff protect your privacy by:

a. Not letting people watch?
b. By making sure you are properly clothed or covered?

5. Does staff ask if someone can stay during medical/hygiene assistance or rehabilitation therapies?
6. Do staff knock on closed doors and wait to be asked in before entering?
7. Are you given privacy when you are using the toilet? In the bathroom? On bed pan or urinal? On bedside commode?
8. Are you given privacy during G-tube feedings? (if applicable)
9. Are privacy curtains/blinds or doors closed for privacy as needed?
10. Does anything about privacy concern you?

11. Are you provided with a place where you can make or receive private telephone calls?
12. Do you receive and send mail unopened?
13. Does the staff mail letters you have written without reading them?
14. Have you heard staff talking about another resident's condition?
15. When you have visitors (family, residents, etc.) can you see them in private?
16. Does staff provide you with a room or a space where you can visit privately?
17. Can you visit with whomever you wish?

18. Can you have visitors anytime you choose?
19. Have you been annoyed by anyone visiting your room when you don't want them?
20. Have staff requested permission to release the records or record information to others?
21. Have you requested to view or copy your records?
22. If so, what did you have to do to view or copy resident records?

STAFF INTERVIEW:

In interviewing staff concerning confidentiality of records, ask the following questions:
1. How do you insure the privacy of the residents' records?
2. What procedures or policies are in place to protect record privacy?
3. What is your responsibility in providing privacy of records?

SELF SURVEY MODULE
483.13 RESIDENT BEHAVIOR & FACILITY PRACTICES
TAG F221

REGULATION:
F221 (a) Restraints
The resident has the right to be free from any physical or chemical restraints imposed for the purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

F221 is used for deficiencies concerning physical restraints.
F222 is used for deficiencies concerning chemical restraints.

INTENT:
The intent of this requirement is for each person to reach his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

DATA COLLECTION:

OBSERVATIONS:
1. How does the device enable the resident to have a higher functional or activity level?
2. Self-releasing device -- can resident release it?
3. Type of restraint (belt, vest, etc.)
4. Type of chair
5. Type of pillows
6. Siderails position
7. Device applied properly
8. Device clean and in good repair
9. Behavior of resident -- cognitive status
10. Verbalization of resident
11. Ambulatory status
12. Bed mobility
13. Transfer status (ambulated to dining room; ambulated to bathroom, etc.)
14. Medical treatment being rendered
15. Visible injuries, especially on extremities
16. Contracture status
17. Staff's conduct in relation to releasing device (positioning resident, etc.)
18. Observation frequency by staff
19. Does resident appear comfortable?
20. What is the resident doing while restrained?
21. How does resident react when approached by others?
22. Is resident interacting with others?

DOCUMENTATION:
Documentation should include assessment, observation, interview, interventions, results, plans of care, and re-evaluations.

A. Assessment data includes the MDS and summary of restraint RAP guidelines. The guidelines focus on need, problem, and risk factor. Information from the guidelines that should be documented include, but not limited to the following:

1. Reason the restraint is used
    a. What medical symptom is being treated?
    b. Is it a behavioral problem? If so, what is the behavior?
    c. Is there danger of falling? If so, what physical factor contributes to this danger?
    d. Is the resident interfering with medical treatment? If so, what specifically does the resident do?
    e. Is the resident's ability to be more self-sufficient enhanced? If so, how?

2. Resident's response to the restraint
    a. What is the resident's behavior while restrained?
    b. How does this behavior differ from behavior when not restrained?

3. Alternative to restraints
    a. Alternatives to restraints that have been used to treat the problem identified above, over what period of time, and under what circumstances?
    b. What was done to change/control behavior before the restraint was applied?
    c. What treatment has been provided to prevent falls before a restraint was applied?

*** Refer to the Restraint RAP Guidelines for a complete guide to assessment.

B. Observation documentation should include the results from observations as indicated under the "Observation" section of this module.

C. Interview documentation should include the families, staff, and resident concerns. Does the resident accept or reject? How were these issues addressed?

D. Documentation of interventions include the alternatives to restraints and the less restrictive restraints actually used as well as the period of time, time of day, and circumstances in which they were used. This information could be covered in the documentation of assessment.

E. Documentation of the results of restraint use should include the actual restraint used, during what time of day it was used, where the resident is located when restrained, who is with the resident at the time, and what actively is occurring in resident's

immediate vicinity at the time of the restraint? Result would include the status of the actual problem for which resident was restrained.

Example: Is the desired behavior exhibited? Has the physical danger been eliminated? Is treatment proceeding as desired?

F. Documentation of Plans should include plan to re-evaluate for use of alternatives and/or less restrictive devices. The care plan should document:

1. The medical symptom for which the restraint is used.
2. The plan for reducing the restraint. Example: gradually increasing the time for ambulation and muscle strengthening.
3. The intervention to prevent complications from restraint use or risks of decline.
4. The interpretive guidelines for Tag F221 list the following interventions that the facility might incorporate in the care planning process:
    - Providing restorative care to enhance abilities to stand safely and to walk;
    - A trapeze to increase bed mobility;
    - Placing the bed lower to the floor and surrounding the bed with a soft mat;
    - Equipping the resident with a device that monitors attempts to arise;
    - Providing frequent staff monitoring at night with periodic assisted toileting for residents attempting to arise to use the bathroom; and/or
    - Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information.

G. Documentation of re-evaluating would include all the factors in the initial evaluation.

INTERVIEWS:

RESIDENT INTERVIEWS:

1. What is this device? (pointing to the restraint)
2. Why do you have this device on?
3. Has anyone talked with you about using this device?
4. Do you know why the facility wants you to use this?
5. Do you know what a restraint is?
6. Do you understand the risks of using a restraint?
7. Do you understand how a restraint can help you?
8. Has anyone told you what choices/types you have if you do not use a restraint?
9. Do you feel that you have a choice of whether you will be restrained or not?
10. How do you feel about using the restraint?
11. When do you wear this device?

FAMILY INTERVIEWS:

1. Why is your loved one restrained? For what reason, explain.
2. At what times of the day is your family member typically restrained?
3. When does your family member wear the device?
4. How often is your family member checked on while restrained?
5. What do staff do at this time?
6. What options to restraining were explored prior to the use of the restraint?
7. Do you believe that the least restrictive type of restraint is being used?
8. Were you consulted prior to the use of the restraint?
9. Were you informed of the benefits/risks associated with restraints?
10. Was your family member informed of the benefits/risks associated with restraints?
11. What does your family member do while being restrained? Specifically, activities/behaviors?
12. Can your loved one walk? Does the staff allow/assist him/her to walk?
13. How does your family member respond?
14. Does the staff take your family member to the bathroom?
15. Have you noticed any change in your loved one (physically/emotionally)?
16. Does he/she wander?
17. How long have restraints been used?
18. How do you feel about the restraint?

EMPLOYEE INTERVIEWS:

CHARGE NURSES: DIRECTORS OF NURSING:

1. How long have you worked with the resident?
2. What medical symptom is being treated?
3. What alternatives have been attempted?
4. What behaviors has the resident exhibited?
5. Is the resident restrained at night? What behavior does the resident exhibit at night?
6. When was the restraint last evaluated?
7. Is the resident incontinent? How often is the resident toileted?
8. What input/involvement has the resident had, family had?

NURSE AIDES:

1. How long have you worked with the resident?
2. Why is the resident restrained?
3. How often do you restrain the resident? Is there any type of restraint schedule for this resident?
4. Is this resident incontinent? How often do you toilet the resident?
5. Do you restrain the resident at night? Is the resident toileted at night?
6. What have you noticed the resident does when the resident is restrained? -- During the day? At night?
7. Have you noticed any changes in the resident (physically or emotionally)?

SOCIAL WORKERS:

1. Why is the resident restrained?
2. What type of participation have you had in helping reduce the resident's restraint?
3. What behavior does the resident exhibit?
4. Why do you think the resident attempts to walk unassisted? Wander out of the building? To go to the bathroom?
5. What past experiences might contribute to the wandering?
6. Is there any time of day that the resident attempts to wander?
7. Tell me why the resident is restrained?
8. When does the behavior occur (day, night, at all times)?
9. Why do you think the resident does this?

THERAPISTS:

1. Why is the resident restrained?
2. Have you been involved in the restraint use or reduction of the restraint for this resident?
3. What types of least restrictive measures have been made?
4. What type of schedule is the resident on for restraints?
5. What is the resident's functional status?
6. Can the resident ambulate or has the resident ever been evaluated for ambulating?

ACTIVITY DIRECTORS:

1. Why is the resident restrained?
2. Have you been involved in restraint use and/or reduction?
3. Is the resident restrained all the time?
4. What behavior have you observed the resident exhibiting that would warrant restraint use?
5. What type of programming have you provided for this resident while restrained? When not restrained?

SELF SURVEY MODULE

F223

§483.13(b) Abuse

The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.

Intent §483.13(b)

Each resident has the right to be free from abuse, corporal punishment, and involuntary seclusion. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the resident, family members or legal guardians, friends, or other individuals.

Interpretive Guidelines §483.13(b) and (c)

"Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish." (42 CFR §488.301)

This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial wellbeing.

This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish.

"Verbal abuse" is defined as the use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; saying things to frighten a resident, such as telling a resident that he/she will never be able to see his/her family again.

"Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault.

"Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment.

"Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation.

"Involuntary seclusion" is defined as separation of a resident from other residents or from her/his room or confinement to her/his room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other Residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs.

Investigation of possible involuntary seclusion, may involve one of two types of situations: that in which residents are living in an area of the facility that restricts their freedom of movement throughout the facility, or that in which a resident is temporarily separated from other residents.

• If the stated purpose of a unit which prevents residents from free movement throughout the facility is to provide specialized care for residents who are cognitively impaired, then placement in the unit is not considered involuntary seclusion, as long as care and services are provided in accordance with each

resident's individual needs and preferences rather than for staff convenience, and as long as the resident, surrogate, or representative (if any) participates in the placement decision, and is involved in continuing care planning to assure placement continues to meet resident needs and preferences.
• If a resident is receiving emergency short-term monitored separation due to temporary behavioral symptoms (such as brief catastrophic reactions or combative or aggressive behaviors which pose a threat to the resident, other residents, staff or others in the facility), this is not considered involuntary seclusion as long as this is the least restrictive approach for the minimum amount of time, and is being done according to resident needs and not for staff convenience.

483.13 (c) STAFF TREATMENT OF RESIDENTS
TAG F224

§483.13(c) Staff Treatment of Residents (F224* and F226**)

The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.
§483.13(c)(1)(i) Staff Treatment of Residents
(1) The facility must--
(i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;

*** Intent §483.13(c) (F224)**
Each resident has the right to be free from mistreatment, neglect and misappropriation of property. This includes the facility's identification of residents whose personal histories render them at risk for abusing other residents, and development of intervention strategies to prevent occurrences, monitoring for changes that would trigger abusive behavior, and reassessment of the interventions on a regular basis.
* Use tag F224 for deficiencies concerning mistreatment, neglect, or misappropriation of resident property.
*** Guidelines §483.13(c) (F224)**
"Neglect" means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (42 CFR 488.301)
"Misappropriation of resident property" means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent. (42 CFR 488.301)

DATA COLLECTION:
OBSERVATIONS:
A. Witnessing an Incident
During any encounter or visit with residents, an observation of verbal or physical abuse, neglect of services, or involuntary seclusion could occur. If this occurs, the incident should be documented with the following information:
1. Who was involved?

2. What was observed?
3. Where did it occur?
4. When did it occur?
5. How did those involved behave and respond?

Ensure the resident is safe and immediately report observations to the administrator.

Following notification, observe actions taken by staff:

1. Do they comply with the facility's policies and procedures?
2. Are residents protected from similar incidents?

B. Abuse

Besides the actual observation of an abusive incident, signs of possible past abuse can be observed in resident, staff, and visitor interactions. Possible signs of previous abuse include:

1. Unexplained bruises or other injuries;
2. Combativeness on the part of a resident towards a particular person;
3. Presentation of fearful or avoidance behavior.

C. Neglect

The observation of neglect may be seen by repeated requests for assistance or the failure to have been provided necessary services. This can be observed with an individual resident or group of residents. Possible signs of neglect may appear by considering:

1. What has happened to the resident as a result of neglect?
2. Are there signs of skin breakdown, dehydration, incontinence, or other symptoms of neglect?
3. How does the resident express the harm he has experienced?

D. Misappropriation

The misappropriation of resident's property is observed when an item is removed from a resident's possession for no apparent reason and without the resident's consent.

With the observation of an incident which may be indicative of abuse, neglect or seclusion, or misappropriation of property, determine if the occurrence was isolated or can a pattern be detected:

1. Is one resident involved or are a group of residents affected?
2. Did the incident occur to the resident(s) being cared for by a particular staff person, at a particular time (i.e., mealtimes, weekends, etc.), or during a particular activity or task?

*** Use other sources of information to identify the nature of the problem.

ABUSE INTERVIEWS:

RESIDENT INTERVIEW:

1. Can you tell me what happened? When?
2. Has this happened before?
3. Is it happening less or more often now?
4. Can you tell me what brought it on?
5. Have you reported it? To whom?
6. Has any staff member talked to you about this?
7. Have you seen or heard of this happening to others?
8. Do you know what, if anything, is being done to prevent it?
9. Can you identify the resident, staff person, or other?
10. Does this occur at any one particular time of day?

11. Are you afraid now?

FAMILY INTERVIEW:

1. Have you seen or heard abuse towards any resident? From staff, another resident, or others?
2. Can you identify these residents? Staff or others involved in these incidents?
3. Has your family member been affected?
4. Have you reported this? To whom?
5. Do you know what is being done to protect your family member from reoccurrence?
6. Are you satisfied with the facility's response and investigation?

GROUP INTERVIEW:

1. Have you seen or heard abuse towards any resident? From staff, another resident or others?
2. Can you identify any of these residents? Staff or others involved in these incidents?
3. Have you ever filed a grievance concerning any resident, staff or others relating to verbal or physical abuse?
4. Did the facility respond?
5. Is it any better now?
6. Are you afraid?
7. What is the facility doing to protect you or prevent reoccurrence?

STAFF INTERVIEW:

1. Do you know what your policies are concerning the prevention and reporting of abuse?
2. How is it implemented? How do you know it has worked?
3. Have residents been identified who are at risk for being abused by others or for mistreating other residents?
4. How do you monitor those residents that have been identified as being at risk for being abused or for mistreating others? Has this been incorporated in the care plan(s)?
5. Has an inservice been held on recognizing/preventing abuse? Staff interventions?

6. Can you explain why reoccurrences have occurred?
7. What has the facility done? Have incidents been investigated? Reported?
8. What have you been directed to do? Did you fill out an incident report?
9. Do you know how to provide care/supervision to this resident to protect/ensure a safe environment for other residents?
10. What does the care plan say?
11. Are the residents reporting the incidents reliable and accurate?
12. The resident assessment shows them as cognitive and alert. Do you agree?
13. This is what the residents are reporting. Is it accurate? If not, why not?
14. Are you aware of the frequency that a specific resident is verbally or physically mistreating other residents?
15. Are you aware that the residents are afraid of this resident?
16. Have you responded to the complaint from the Residents' Council?
17. Has this resident been evaluated by a psychiatrist?
18. Has the resident's primary care physician been advised of the problem?
19. How is the behavior being managed medically? Staff approaches?
20. How was it managed previously?
21. Has the care plan been updated?

22. Has your social worker been involved with the resident with the behavior problems?
23. What are the social worker's suggestions?
24. Have you reported the incident to the State agency or do you have knowledge that it was reported?
25. Have you completed your investigation?
26. What have you done as a result of the identified problem? Staff training, resident interventions, environmental changes?
*** Staff interviews should involve all who may or should have knowledge of an incident or unusual occurrence which has occurred in the facility. Therefore, the focus of the questions should be adjusted as one interacts with the various staff, potentially from any department.

NEGLECT INTERVIEWS:

RESIDENT INTERVIEW:

1. Can you tell me how this (harm) occurred? What happened? Who was involved?
2. What do staff usually do?
3. Has this happened before? If so, how frequently?
4. What do you expect staff to do to prevent these results?
5. How did you feel? How do you feel?
6. Do you feel this was avoidable?
7. Was your physician notified? How was this treated?
8. Did you report this to staff? To whom? What were you told?

FAMILY INTERVIEW:

1. Were you notified?
2. Has this happened before?

3. Do you feel this was avoidable?
4. Can your family member indicate his/her need for services/care? Does your family member resist care? How frequently?
5. Did the facility investigate what has happened?
6. Are you aware of the results of any investigation?
7. Are you satisfied with the facilities response?
8. Did you report this to staff? To whom? What were you told?

GROUP INTERVIEW:

1. Are you aware of any event where a resident became injured as a result of the facility not providing a service of care?

*** Information obtained may require individual follow-up.

STAFF INTERVIEW:

1. Can you tell me what happened? When?
2. Can you explain why? Was the resident to any extent accountable?
3. What did you do when it was discovered?
4. Was an incident report filed?
5. Is the resident reliable in what they tell me?
6. This is what the resident says happened. Is it accurate?
7. Do you know the care plan for this resident?
8. Tell me what you do for. . .
9. Has this happened before?
10. Was the incident investigated? What was the result of the investigation?

11. How are you preventing this from reoccurring?
12. What is your policy for residents with similar needs as this?
13. Have any other residents had a similar incident?
14. How do you usually treat this resident for this issue?

MISAPPROPRIATION OF PROPERTY INTERVIEWS:

RESIDENT INTERVIEW:

1. Can you tell me what items you have missing?
2. Did you report it to anyone? Who?
3. Did the facility investigate your missing items?
4. Do you know the results of the investigation?
5. Have you had things missing before?
6. Do you get a monthly statement on your account?
7. Do you know what you have to pay for out of it?
8. Who takes care of your account?
9. Have you questioned withdrawals from your account?

FAMILY INTERVIEW:

1. Do you understand what is paid for and what is not paid for with this account?
2. Do you have problems with personal property getting lost?
3. Have you reported it? To whom?
4. Are you satisfied with their investigation and the results?

GROUP INTERVIEW:

1. Are you having problems with missing personal items?
2. What do think is happening to them?
3. Have you reported it?
4. Did the facility investigate your complaint?
5. What were the results? Were you satisfied?
6. Is the situation better now?

STAFF INTERVIEW:

1. Have you had problems with missing personal items?
2. Are the reporting residents alert and accurate?
3. What policies have you implemented to prevent further missing items?
4. Does the facility admission packet explain what the residents are responsible for paying?
5. How do you handle residents' accounts?
6. Do they receive interest on those accounts?
7. How often do they get a statement?

DOCUMENTATION:

Observations and interviews lead to documentation. Look for appropriate sources of documentation based on the nature of the allegation (abuse, neglect, or misappropriation of resident property) and likely perpetrator (perpetrator unknown, another resident, a staff member, a family member or visitor, or facility culture).

Does the facility have written policies and procedures to prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property?

1. Does documentation indicate that they are followed?
2. How have the incidents been processed?
3. Is there documentation that they have reported to the State Agency? Department of

Social Services?
4. Have they been investigated by the facility in a timely manner?
5. Is there documentation that the facility has taken appropriate actions following the investigation(s) and that those actions have been effective?

DOCUMENTATION OF ABUSE:

1. Documentation that the facility policy is in place, is being followed and has been effective.
2. Was there an investigation initiated and completed by the facility? Were the results documented?
3. Review the resident assessment instruments (i.e., the MDS, etc.) of the resident or residents involved in the abusive incident or report.
4. Review the Care Plan to see if the combative behavior has been identified and preventive measures put in place.
5. Review Nurses' Notes and Accident/Incident reports or log to determine frequency of resident to resident combative incidents.
6. Review Resident Council minutes for resident complaints about physical, verbal abuse by staff, residents or others. What was the facility's response?
7. Documentation that the attending physician is aware of the problem. How has he/she helped address the issue (i.e., staff interventions, referrals, medication changes, etc.)?
8. What has the Social Worker's notes identified and how is it being addressed?
9. Has a cause or stimulus of the combative behavior been identified?
10. How is the resident being monitored, what is being monitored, and is such monitoring effective?
11. Verify the cognition and credibility of the resident reporting the abuse via the assessment instrument and medical record review.
12. How has the resident been protected from further abuse (care planned, monitoring sheets, visitation arrangements, personnel action, etc.)?

DOCUMENTATION OF NEGLECT/INJURY OF UNKNOWN ORIGIN:

1. Do Nurses' Notes describe when, what, how, and what harm did occur?
2. Documentation that an incident report was filed?
3. Documentation that appropriate people/agencies were notified?
4. Check care plan and assessment to see if the resident refused treatment or services. How frequently? Were other staff approaches attempted?
5. Check the resident assessment to determine the resident's cognitive status.
6. Was there an investigation? If so what were the results?
7. What was the resident's Plan of Care to prevent such harm? What service was neglected? Has it reoccurred?
8. What should have been done according to the facility? What actually occurred?
9. Was there documentation of training or in-services provided regarding areas of concern?
10. Is there a policy for the treatment of other residents with the same care issue?
11. Is the treatment expected as a standard of practice?
12. Review records of other residents who may or have been affected by the same practice or assigned to the same staff person?

DOCUMENTATION OF MISAPPROPRIATION OF PROPERTY:

1. Review records of the personal items and furnishings brought to the facility at the time

of admission.
2. Review documentation of monthly bank statements.
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3. Verify deposits and interest earned.
4. Verify withdrawals.
5. Verify those items/costs for which the resident maintains responsibility.
6. Verify that the amounts withdrawn for services is equal to the charges for those services.
7. Verify cognition and credibility of resident reporting loss via resident assessment instrument and Nurses' Notes.
8. Any Nurses' Notes or Social Work's notes regarding the reported incident?
9. What was the facility’s response to resident/family regarding the allegation?
10. Is there a policy to investigate reported resident loss and allegations of misappropriation?

SELF SURVEY MODULE
483.13 (c) STAFF TREATMENT OF RESIDENTS
TAG F226

REGULATION:
F226(c) Staff Treatment of Residents
The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect and abuse of residents and misappropriation of resident property.

F226 is used for deficiencies concerning the facility's development and implementation of policies and procedures.

INTENT:
The facility must develop and operationalize policies and procedures for screening and training employees, protection of residents and for the prevention, identification, investigation and reporting of abuse, neglect, mistreatment, and misappropriation of property. The purpose is to assure that the facility is doing all that is within its control to prevent occurrences.

OBSERVATIONS: General
Resident and staff behaviors and interactions are observed throughout the entire survey.
Indications that staff are neglecting or abusing residents
Are staff showing indications of stress
Observe how staff respond to safeguard residents and report concerns.

Observe:
1. Are an adequate number of staff available to meet residents' needs. If staff have called in what measures are put into place so that care is provided?
2. Is there adequate supervision of staff to identify stress reactions and possible neglect and abuse situations.
3. Staff (direct care and managers) response to handling resident to resident conflict (assistance to room, redirection)
4. Staff response to resident's resistance to care (rough in handling, verbally threatening)
5. Staff supervision of residents with elopement potential or intrusive wandering.
6. Unusual injuries or bruising of residents.
7. Staff response to resident's requests and needs are these met in a timely and appropriate manner.
8. Staff behavior (loud, angry voice, roughness or abruptness in care delivery, verbal or physical threats)
9. Staff (direct care, managers, and administrative) response to observed or reported inappropriate staff behavior.
10. Staff (direct care, managers, and administrative) response to observed or reported inappropriate visitor behavior.
11. Physical Environment: Clean, uncluttered equipment in proper working repair.

12. If training is being provided on abuse and neglect observe the training.
13. Observe the current physical and psychological health of the victim as well as current staff interaction with this individual and other receiving services.

RECORD REVIEW:

- Review facility's policies/procedures and record documentation. Do they include the following components and are these components operationalized? : (All of the following are not required, but are examples of what makes up a good program/policy and procedures).
- **Screen** potential applicants for a history of abuse, neglect or mistreating residents?
    - Does the provider have a comprehensive interview process for potential hires?
    - Does the provider check and documents references beyond the minimum information that is legally required?
    - Does the provider check the prospective employee's work history?
    - Does the provider check criminal background for direct care staff?
    - Check Personnel files for references, work history, criminal background check, qualifications and training records
    - Review staff schedules to confirm adequacy of staffing based on need and observations of individuals receiving services. Do staff volume and qualifications match individual needs?
    - Review provider's methods for detecting and preventing abuse and neglect and/or data pertinent to recruitment and /or hiring practices.

- **Train** employees through orientation and ongoing sessions on issues related to abuse prohibition practices?
    - Training for employees should include the following:
        - Basic communication skills
        - Conflict resolution and anger management
        - Clinical presentation of dementia, mental illness, developmental disabilities, cognitive impairment and strategies for communication
        - Effect of cognitive impairment on communication and function
        - Successful ways of coping with maladaptive behaviors.
        - Knowledge of and respect for individual rights
        - Staff behaviors that can elicit negative responses by individuals receiving services.
        - Effect of disease specific and age related changes.
        - Approaches and care necessary to detect and prevent feelings such as loss of control and resulting depression
        - Restorative care that utilizes commonly accepted approaches to help the individual function at his or her optimal level.
        - Promotion of individual rights.

- Check training records for evidence that staff have received upon orientation and on a regular basis thorough and accurate training regarding abuse and neglect:
  - Education on individual rights
  - Conflict resolution training
  - Coping with maladaptive behaviors.
  - Education on cognitive challenges, mental illness, dementia, developmental disabilities, including communication techniques.
  - Meeting the specific needs of the population.

- **Response**: The facility should provide residents, families and staff information on how and to whom they may report concerns, incidents and grievances and provide feedback regarding the concerns that have been expressed?
  - Are all allegations responded to and treated with the same degree of consideration and seriousness regardless of their nature?
  - Was the response prompt?
  - What care and attention are given to the individuals involved in the incident following the reporting of the incident?
  - Was immediate action taken to protect the victim and to address the behavior of the perpetrator?
  - Review the corrective action plan that should be put into place.
  - What did the facility do in response? Train/retrain staff? Rewrite policies and procedures? Revise the system to better respond?

- **Identification:** Did the facility identify events, occurrences, patterns and trends that may constitute abuse and determine the direction of the investigation? Do the policies and procedures address this?
  - Typical abusers are direct caregivers are often the lowest paid workers in the most understaffed areas of facilities
  - Some times facilities do not take allegations of abuse seriously or the reporter is afraid of retaliation.
  - Does the facility have a method of recognizing factors that lead to abuse and neglect such as job burnout, inability to manage conflict, stress and insufficient training?
  - Many times perpetrators are male, new hires and second-shift workers
  - Low wages and poor benefits, compounded by the emotional and physical strain of the work contribute to quality control problems in long term care.
  - Review the administrative structures such as the policy and procedures to see if they are contributing to abuse and neglect problems.
  - External factors such as employment levels and pay rates can affect staffing.
  - Tradition: long-standing practice in some settings can discourage attachment between individuals receiving services and those providing services.
  - Isolation: some individuals who live in institutions are isolated and have little contact within the community.

- Institutional environment such as the size and physical design of the building can affect the care provided.
- The facility should identify staff characteristics that can contribute to neglect and abuse, such as experience level, educational level, challenging personal life style choices, and ethnic and cultural backgrounds.
- The facility should identify the characteristics of individual receiving services such as dependent, frail, chronically ill, impaired functions, and mentally incapacitated as well as residents being physically or verbally aggressive.
- Review incident reports.

- **Investigate:** Review different types of incidents and identify the staff member responsible for the initial reporting, investigation of alleged violations and reporting of results to proper authorities.
- Do the policy and procedures address how to investigate the incident?

- **Protection:** How does the facility protect residents from harm during an investigation? Do the policy and procedures address this?
  - How does the facility protect the rights of individuals receiving services?
  - Are residents separated? Roommate change or staffing changes?
  - Staff changed, suspended, reassigned to other tasks during the investigation?
  - Is there a policy and procedure to determine if there is a mechanism in place to protect reporters, victims and suspected perpetrators?
  - Does the documentation of the incident reflect efforts to protect the individual from the potential abuser?

- **Report:** Does the facility have a policy and procedure on reporting all alleged violations and all substantiated incidents to the State Agency and all other agencies as required? Does the facility then take all necessary corrective actions depending on the results of the investigation?
  - Has the state agency (health care personnel registry been notified within 24 hours)?
  - Has an investigative report been completed as required?
  - Does the investigation have the following:
    - Individual and caregiver interviews, as indicated?
    - Clinical examination?
    - Staff interviews?
    - Collaboration with state agencies?
    - Methods to support the individual and detect and prevent further victimization.
    - Was the resident examined in a thorough and timely manner?

The Abuse Investigative Protocol requires that the survey team:

1. Review 2-3 alleged violations since the previous time this was reviewed by the state. Review the written evidence to determine how the facility has handled alleged violations. Did the facility implement adequate procedures for:
   Reporting and investigating?
   - Protection of the resident during the investigation?
   - Provision of corrective action?

2. From a list of employees hired within the previous four months, select 5 new hires and review written evidence from the facility that the facility conducted pre-screening checks based on regulatory requirements at 42 CFR 483.13(c).

3. The survey team should interview five direct care staff representing all three shifts, including activity staff and nursing assistants to determine if staff are trained in and are knowledgeable about how to appropriately intervene in situations involving residents that have aggressive or catastrophic reactions.
   -Are staff knowledgeable regarding what, when and to whom to report according to facility polices?

4. Interview at least three front line supervisors of staff who interact with residents (nursing, dietary, housekeeping, activities, and social services). Determine how they monitor the provision of care/services, the staff/resident interactions, deployment of staff to meet the residents' needs and the potential for staff burnout, which could lead, to resident abuse.

5. Interview several residents and families regarding their awareness of to whom and how to report allegations, incidents and/or complaints.

6. Interview the individual(s) identified by the facility as responsible for coordinating the policies and procedures to evaluate how each component of the policies and procedures is operationalized

STAFF INTERVIEWS:
Interviews with Staff:

Administrator:
Describe the entity's admission criteria.
What practices do you have in place for identifying abuse and neglect?
How do you manage risk factors for abuse and neglect?
Do you have an abuse and neglect detection and prevention training program for staff and for individuals receiving care and their families?
How are the abuse and neglect detection and prevention training materials operationalized in daily practice?
What are your policies and procedures for the protection of individuals receiving services?

What happens to individuals who are involved in an incident?
How is their safety assured?
Describe your approach for investigating allegations of abuse and neglect?
Was this process followed?
Has the response process been evaluated?
Have there been revisions in this process or in related operations?

Staff:
Describe the interview process for your position?
How were you trained?
Are you aware of a protocol to use when you feel you need assistance in conducting a care task.
Who is your supervisor and is he/she available when you need him/her?
Have you observed any abuse or neglect?
If so, was a report made? How was the situation handled?
Has staff been involved in identifying abuse or neglect? If so what was the response of management?
Have you been trained in the detection and prevention of abuse and neglect?
Do you know the polices and procedures for reporting abuse and neglect?
Describe any training you have received addressing abuse and neglect?
Are you protected from intimidation and harassment as the result of reporting an incident?
Have things changed as a result of incidents you may have reported?
For better or worse?
To whom would you report an incident of alleged abuse or neglect?
What would you do if you discovered an incident of abuse or neglect involving an individual with who you work?
Who would you tell about what you heard or observed?
Refer to a specific situation and describe what happened.
How was the incident investigated?
What were the findings?
What was the planned course of action?
How promptly do you receive a response to your report if at all?
How are individuals protected, how are they treated, what actions is taken?
Do you feel that you are protected from intimidation and harassment as a result of reporting an incident?

Individual/Family:
Does staff respond to your needs in a timely manner?
Does staff appear to be rushed? (This may suggest inadequate volume to meet individual needs).
Do staff appear to be competent and well trained?
Have you been provided training about abuse and neglect?
To whom would you report incidents of alleged abuse or neglect?
What would you do if you felt you had been abused or neglected?

What would you do if you discovered an incident of abuse or neglect involving an individual with whom you live?
Do you believe that your complaint was responded to in a timely manner?
Tell me about the investigation?
Did you feel safe while the investigation was happening?
Do you feel safe now?
Do you know what to do if you suspect abuse and neglect?
How does the provider respond to reports of abuse and neglect?
Have you ever been abused or neglected?
If so, have you made a report?
To whom? How were you treated?
Did you feel safe?
Have things changed as a result of incidents that you have reported?
For better or worse?
How promptly do you receive a response to your report if at all?
Do you feel that your are protected from intimidation and harassment as a result of reporting the incident?
Have there been any changes in the quality of your care as a result of the incidents that you have reported?

I. Screening

How do you screen potential employees for a history of abuse, neglect, or mistreating residents? Are you doing criminal background checks? Are these checks different for potential employees based on their length of residence in North Carolina? Are you checking with the nurse aide registry to find out if the applicant has had a finding entered? Are you verifying licenses and registries? Are you attempting to obtain references from previous employers?

II. Training

How do you train staff on abuse prohibition practices? Who attends these sessions? How often are they offered? What does the material cover? Does the material cover: interventions to deal with aggressive / catastrophic reactions of residents? how staff report their knowledge of allegations without fear of reprisal?; how to recognize signs of burnout, frustration and stress that may lead to abuse?; what constitutes abuse, neglect and misappropriation of resident property? Ask **staff**: Can you describe the mission of this organization?

III. Prevention

How do you inform residents, staff and family members on how to report concerns, incidents and grievances without fear of retribution? How do identify, correct and intervene in situations in which abuse, neglect and/or misappropriation are more likely to occur? How do you assure sufficient numbers of staff to meet the residents' needs? How

do you supervise the delivery of care? How do you monitor residents who have behavioral problems or histories of aggression?

IV. Identification

How do you identify events, patterns and trends that may constitute abuse? How do you determine the direction of the investigation? Ask **Administrator** what methods or approaches for detecting and preventing abuse and neglect have you initiated since the last survey? What were the outcomes?

V. Investigation

Do you have procedures to investigate different types of incidents?

VI. Protection

How do you protect residents from harm during an investigation?

VII. Reporting/Response

To whom are you reporting alleged violations and substantiated incidents? When are you reporting to the Nurse Aide Registry or licensing authority? How do you analyze occurrences to determine what changes, if any are needed to the current policies and procedures?

Interview at least five direct care staff, representing all three shifts, including activity staff and nursing assistants, to determine if staff are trained in and are knowledgeable about how to appropriately intervene in situations involving residents who have aggressive or catastrophic reactions. Do staff know what, when and to whom to report according to facility policies?

Interview at least three front line supervisors who interact with residents.
Determine how they monitor the provision of care/services, the staff/ resident interactions, deployment of staff to meet the residents' needs, and the potential for staff burnout, which could lead, to resident abuse.

Interview residents and their families.
Do you know if the facility has policies and procedures for detecting and preventing abuse and neglect? If yes, please describe policies and how you were made aware of them.

SELF SURVEY MODULE
483.15 (a) DIGNITY
TAG F241

REGULATION:
F241 (a) Dignity
The facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality.

INTENT:
To the resident's way of thinking about themselves and others, the intent of the dignity tag is to create a way of living in a group setting that allows residents to be comfortable and happy by making the resident feel they are valuable as unique people.

DATA COLLECTION:

A. Things to think about
    1. In every area of the residents' life we must focus on how the residents feel about every part of their lives at the facility.
    2. Dignity issues may also include how the residents feel that other residents are being treated.
    3. Be aware of what residents want their life and care routines to be like, and try to do things that way as much as possible, not for staff convenience.
    4. Residents are individual people, not objects and not just members of a group of people.

OBSERVATIONS:

A. "Where do we look for dignity and what do we look for?"

    1. Look everywhere and look at everything.
        a. In every part of the facility, inside and outside.
        b. Even the smallest problem can become a dignity issue if it makes a resident feel badly about his or her life at the facility.

    2. Look at anything that could affect the way a resident feels about his or her own self-worth as a person.
        a. How people get along.
        b. How people talk to each other.
        c. How people respond to residents' needs and wants will show everyone how much value is placed on the residents.

3. Look at everything ***around*** the resident.
    a. Everything (equipment and people) should work to make sure the resident is comfortable and happy in the facility.
    b. Repair or provide equipment so the residents can use what they need.
    c. Keep the home clean and look for ways to improve residents' ability to get around in and out of the facility.

4. Look at everything involved ***with*** the resident.
    The overall appearance and experiences of residents can tell much about the value placed on their care at a facility:
        a. Grooming as resident prefers
        b. Respect for personal items
        c. Call lights answered timely
        d. Pleasant dining room experience (noise level, table mates)
        e. Respectful care giving

B. Look for dignity the minute you come on the facility property.

1. Use all of your senses:
    a. smell
    b. touch
    c. sight
    d. sound
    e. taste
    f. intuition to observe for dignity issues

2. If you feel uncomfortable with a situation involving residents, then dignity may be involved.

3. Little things mean a lot:
    a. The smallest task such as good grooming (hair, nails, teeth, clothes)
    b. Having time to communicate with staff or complete tasks, can improve a resident's dignity.

4. Dignity is what a resident thinks, feels and believes it is.

<u>INTERVIEWS</u>:

A. Who is interviewed and why
1. The resident is the most important interview, after that there are many sources who have information about the resident's dignity:
    a. Family members
    b. Staff in every department (any employee who knows about the resident's life.

c. Volunteers
d. Visitors: anyone living on the nursing home property, but not a nursing home resident can be considered a visitor.
e. Doctors
f. Resident Council
g. Family Council
h. Ombudsman
i. Community Advisory
j. Committee members
k. Anyone who knows about the resident's life in the facility.

B. Things to think about:

1. Questions should center around the ***residents' feelings*** about their life at the nursing home.
2. Be aware that residents will often feel emotions such as fear or loyalty that will influence their answers.
3. Interview questions should start off seeking broad information. Use the answers to ask questions that will gain more specific facts.
4. Having a variety of all levels of staff interview residents may give a different point of view to both staff and resident and may result in more useful information.
5. Let the answers to interview questions lead you to asking questions about other parts of the resident's life. Dignity issues may lead to questions regarding staffing patterns, schedules, activities, or social services.
6. The facility should be able to show through documentation how they have tried to solve or address the issues brought up by the resident, the family or others.

RESIDENT INTERVIEW:

1. How do you feel about your life here at the facility?
2. How is it here for you?
3. Are you getting the help you need?
4. Tell me about the help you get here.
5. Help me understand about your situation here.
6. How are you treated by the staff?

*** These questions can often be followed by "Is this your choice?"

FAMILY INTERVIEW:

1. In what condition do you find the resident when you visit?
2. Have you ever had any problems or concerns about the care here?
3. Who is aware of your concerns, and what have they done to help resolve them?
4. Tell me about your family member's situation here.
5. Help me understand what your resident's life is like here.

DOCUMENTATION:

A. Where would it be written and why?
    1. There are numerous places that documentation may be present to demonstrate how a facility is dealing with dignity issues. This is a partial list:
        a. Progress Notes
        b. Assessments
        c. Patient Care Plan
        d. Incident Reports
        e. Resident Assessment Protocol Summaries (RAP's)
        f. Nursing, Social Work, Activity, or Doctor Summaries
        g. Social History, Progress Notes or Confidential files
        h. Activity Notes
        i. Resident Council Minutes
        j. Family Council Minutes
        k. Policy and Procedures Manual
        l. Grievance Policies
        m. Grievance report file
        n. Chaplain's notes
        o. Admissions Packets
        p. Quality Assurance Committee Notes
        q. Restraint Committee Notes

B. Things to Think about:
    1. Documentation should show what is being done for the resident and why, by:
        a. Showing that the event(s) that caused a concern about dignity did occur.
        b. Keeping track of how often the event has occurred (this will establish a pattern, if one exists).
        c. Looking at what has been done by the staff or others in the past to try to resolve the concern.
        d. Using the pattern to decide what to do to help the resident with resolving dignity issues now.
        e. Looking back at the solutions to see if they really helped the resident feel better about their life at the nursing home.

*** Every member of the staff who may be involved with resolving the concerns needs to be aware of what the plan is and how it should be carried out.

SELF SURVEY MODULE
483.15(b) SELF-DETERMINATION AND PARTICIPATION
TAG F242

REGULATION:
F242 SELF-DETERMINATION AND PARTICIPATION
The resident has the right to --

(1) Choose activities, schedules, and health care consistent with his or her interests, assessments, and plan of care;
(2) Interact with members of the community both inside and outside of the facility; and
(3) Make choices about aspects of his or her life in the facility that are significant to the resident.

DATA COLLECTION:

OBSERVATIONS:

A. The Resident
1. How is the resident dressed?
2. Is their dress for their age, sex, physical condition and preference?

B. The Room
1. Is the room furnished with personal furniture and/or pictures or other personal items?
2. Is the radio or television on/off and consistent with the resident's interests or preferences?

C. Staff/Resident Interaction:
1. Does the staff ask the resident questions to determine the resident's preferences? For example:
    a. When would you like to get up in the morning?
    b. Is there anything special you would like to do today?
    c. It is time for your scheduled bath? Are you ready?
2. How does staff respond to the resident's preferences?
3. Is the resident given choices regarding his or her personal appearance?
4. If the resident states a preference, how does the staff respond?

D. Daily Life
1. Does the resident's daily schedule and activities reflect the ongoing resident's interests and needs?
2. During meal observations do residents receive food/beverage items consistent with preferences recorded on the tray card?

DOCUMENTATION:

A. Minimum Data Set (MDS)
    1. Review the MDS for information on resident's preferences and needs.

B. Care Plan:
    1. Review the care plan to see if it incorporates the resident's likes and dislikes.

C. Social Worker's Notes in the Medical Record:
    1. Does the initial assessment and progress notes give information regarding previous lifestyles and preferences?

D. Dietary Notes in the Medical Record:
    1. Does the initial assessment and progress notes identify food/beverage preferences?
    2. Is the documentation on the tray card reflective of these preferences?

E. Nurses' Notes in the Medical Record:
    1. Review the nurses' notes to see evidence of preferences honored or requested.

F. Resident Council Minutes:
    1. Review Resident Council minutes to determine if the needs and preferences are being honored?
    2. Activity notes in the medical record. Does the initial assessment and progress notes identify the residents' hobbies and interests?

INTERVIEWS:

RESIDENT INTERVIEWS:

A. Resident Interview about the Room:
    1. How do you feel about your roommate?
    2. Do you enjoy spending time in your room?
    3. Is there enough light for you?
    4. Is the room temperature comfortable?
    5. Is there anything you would like to change about your room?
    6. Have you told the staff about room preferences you have?

B. Resident Interview about Activities:
    1. What kind of activities do you attend?
    2. Do you enjoy the activities?
    3. Do you go outside of the facility for activities?
    4. Is there an activity you would like to do other than the activities that are offered here?
    5. Have you told the staff about activity preferences that you have?

C. Resident Interview about Decisions:

1. Does staff consider your choices when providing daily nursing care and medical treatment?
2. When a preference is stated do you participate in meetings where staff help identify areas of needs and then plan your daily activities, medical and nursing care?
3. If staff are not able to honor your request, do they inform you why?
4. Can you choose how you spend the day?
5. Has anyone talked with you about your food and drink preferences?
6. If so, does staff honor those preferences at mealtime?
7. Do you have the opportunity to participate in meetings where staff help identify areas of need and then together plan your daily activities, medical and nursing care based on your individual needs and preferences?

FAMILY INTERVIEWS:

A. Family Interviews for Noninterviewable Residents

1. Do you know your family member's daily routine preferences when he/she was able to make the choices and tell you what he/she wanted?
2. Did he/she enjoy particular hobbies or activities?
3. Is/was there an interest in spiritual or religious activities?
4. Was he/she more of a social person or a loner?
5. What types of social or activities did he/she attend?
6. Are there any particular food or beverage preferences or special eating habits?
7. What was his/her sleeping habit or pattern?
8. What was his/her lifetime work?

B. Family Interview for Interviewable or Noninterviewable Residents

1. Is there anything about your family member that you feel is important to know?
2. Did the facility staff ask you about your family member's preferences and have they incorporated these into their daily care of your family member?

GROUP INTERVIEW:

1. Are there any special rules here? (i.e., certain times you have to go to bed, get up, bathe, etc.?)
2. Do you have input into the rules at this facility?
3. Does the facility listen and respond to your suggestions?
4. Do the activities here meet your interest and needs?

STAFF INTERVIEW:

1. Is there anything "special" that the resident likes to do, have or wear?
2. Is the staff caring for the resident aware of the resident's preferences?
3. Can you tell me what the resident's preferences are?
4. How do you know what your assigned residents like or do not like?
5. What do you do when a resident states a preference to you?

6. Are residents reminded that they have a choice?
7. How do you offer the resident choices?

SELF SURVEY MODULE
483.25 (c) PRESSURE SORES

REGULATION:
F314
§483.25(c) Pressure Sores

Based on the comprehensive Assessment of a resident, the facility must ensure that--
(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.
Intent: (F314) 42 CFR 483.25(c)
The intent of this requirement is that the resident does not develop pressure ulcers unless clinically unavoidable and that the facility provides care and services to:
• Promote the prevention of pressure ulcer development;
• Promote the healing of pressure ulcers that are present (including prevention of infection to the extent possible); and
• Prevent development of additional pressure ulcers.
NOTE: Although the regulatory language refers to pressure sores, the nomenclature widely accepted presently refers to pressure ulcers, and the guidance provided in this document will refer to pressure ulcers.
DEFINITIONS
Definitions are provided to clarify clinical terms related to pressure ulcers and their evaluation and treatment.
• "Pressure Ulcer"- A pressure ulcer is any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s).[1] Although friction and shear are not primary causes of pressure ulcers, friction and shear are important contributing factors to the development of pressure ulcers.
• "Avoidable/Unavoidable" Pressure Ulcers
o "Avoidable" means that the resident developed a pressure ulcer and that the facility did not do one or more of the following: evaluate the resident's clinical condition and pressure ulcer risk factors; define and implement interventions that are consistent with resident needs, resident goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.
o "Unavoidable" means that the resident developed a pressure ulcer even though the facility had evaluated the resident's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.
• "Cleansing/Irrigation"
o "Cleansing" refers to the use of an appropriate device and solution to clean the surface of the wound bed and to remove the looser foreign debris or contaminants in order to decrease microbial growth.[2]
o "Irrigation" refers to a type of mechanical debridement, which uses an

appropriate solution delivered under pressure to the wound bed to vigorously attempt to remove debris from the wound bed.[3]

- "Colonized/Infected" Wound [4, 5]
  - "Colonized" refers to the presence of bacteria on the surface or in the tissue of a wound without the signs and symptoms of an infection.
  - "Infected" refers to the presence of micro-organisms in sufficient quantity to overwhelm the defenses of viable tissues and produce the signs and symptoms of infection.
- "Debridement"- Debridement is the removal of devitalized/necrotic tissue and foreign matter from a wound to improve or facilitate the healing process. [6, 7, 8] Various debridement methods include:
  - "Autolytic debridement" refers to the use of moisture retentive dressings to cover a wound and allow devitalized tissue to self-digest by the action of enzymes present in the wound fluids.
  - "Enzymatic (chemical) debridement" refers to the topical application of substances e.g., enzymes to break down devitalized tissue.
  - "Mechanical debridement" refers to the removal of foreign material and devitalized or contaminated tissue from a wound by physical rather than by chemical or autolytic means.
  - "Sharp or surgical debridement" refers to removal of foreign material or devitalized tissue by a surgical instrument.
  - "Maggot debridement therapy (MDT)" or medicinal maggots refers to a type of sterile intentional biological larval or biosurgical debridement that uses disinfected (sterile) maggots to clean wounds by dissolving the dead and infected tissue and by killing bacteria.[9]
- "Eschar/Slough"
  - "Eschar" is described as thick, leathery, frequently black or brown in color, necrotic (dead) or devitalized tissue that has lost its usual physical properties and biological activity. Eschar may be loose or firmly adhered to the wound.
  - "Slough" is necrotic/avascular tissue in the process of separating from the viable portions of the body and is usually light colored, soft, moist, and stringy (at times).
- "Exudate"
  - "Exudate" is any fluid that has been forced out of the tissues or its capillaries because of inflammation or injury. It may contain serum, cellular debris, bacteria and leukocytes.
  - "Purulent exudate/drainage/discharge" is any product of inflammation that contains pus (e.g., leukocytes, bacteria, and liquefied necrotic debris).
  - "Serous drainage or exudate" is watery, clear, or slightly yellow/tan/pink fluid that has separated from the blood and presents as drainage.
- "Friction/Shearing"
  - "Friction" is the mechanical force exerted on skin that is dragged across any surface.
  - "Shearing" is the interaction of both gravity and friction against the

surface of the skin. Friction is always present when shear force is present.[10] Shear occurs when layers of skin rub against each other or when the skin remains stationary and the underlying tissue moves and stretches and angulates or tears the underlying capillaries and blood vessels causing tissue damage.

• "Granulation Tissue"

o "Granulation tissue" is the pink-red moist tissue that fills an open wound, when it starts to heal. It contains new blood vessels, collagen, fibroblasts, and inflammatory cells.

• "Tunnel/Sinus Tract/Undermining"-Tunnel and sinus tract are often used interchangeably.

o "Tunneling" is a passageway of tissue destruction under the skin surface that has an opening at the skin level from the edge of the wound.

o A "sinus tract" is a cavity or channel underlying a wound that involves an area larger than the visible surface of the wound.

o "Undermining" is the destruction of tissue or ulceration extending under the skin edges (margins) so that the pressure ulcer is larger at its base than at the skin surface. Undermining often develops from shearing forces and is differentiated from tunneling by the larger extent of the wound edge involved in undermining and the absence of a channel or tract extending from the pressure ulcer under the adjacent intact skin.

INVESTIGATIVE PROTOCOL

PRESSURE ULCER

Objectives

• To determine if the identified pressure ulcer(s) is avoidable or unavoidable; and

• To determine the adequacy of the facility's interventions and efforts to prevent and treat pressure ulcers.

Use

Use this protocol for a sampled resident having--or at risk of developing-- a pressure ulcer.

If the resident has an ulcer, determine if it was identified as non-pressure related, e.g., vascular insufficiency or a neuropathic ulcer. If record review, staff and/or physician interview, and observation (unless the dressing protocol precludes observing the wound) support the conclusion that the ulcer is not pressure related, do not proceed with this protocol unless the resident is at risk for developing, or also has, pressure ulcers. Evaluate care and services regarding non-pressure related ulcers at F309, Quality of Care.

Procedures

Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. For a newly admitted resident either at risk or with a pressure ulcer, the staff is expected to assess and provide appropriate care from the day of admission. Corroborate observations by interview and record review.

1. Observation

Observe whether staff consistently implements the care plan over time and across various shifts. During observations of the interventions, note and/or follow up on deviations

from the care plan as well as potential negative outcomes, including but not limited to the following:

• Erythema or color changes on areas such as the sacrum, buttocks, trochanters, posterior thigh, popliteal area, or heels when moved off an area:
  o If erythema or color change are noted, return approximately ½ - ¾ hours later to determine if the changes or other Stage I characteristics persist;
  o If the changes persist and exhibit tenderness, hardness, or alteration in temperature from surrounding skin, ask staff how they determine repositioning schedules and how they evaluate and address a potential Stage I pressure ulcer;
• Previously unidentified open areas;
• Whether the positioning avoids pressure on an existing pressure ulcer(s);
• Measures taken to prevent or reduce the potential for shearing or friction during transfers, elevation, and repositioning; and
• Whether pressure-redistributing devices for the bed and/or chair, such as gel-type surfaces or overlays are in place, working, and used according to the manufacturer's recommendations.

Observation of Existing Ulcer/Wound Care

If a dressing change is scheduled during the survey, observe the wound care to determine if the record reflects the current status of the ulcer(s) and note:

• Characteristics of the wound and surrounding tissues such as presence of granulation tissue, the Stage, presence of exudates, necrotic tissue such as eschar or slough, or evidence of erythema or swelling around the wound;
• The form or type of debridement, if used;
• Whether treatment and infection control practices reflect current standards of practice; and
• Based on location, steps taken to cleanse and protect the wound from likely contamination by urine or fecal incontinence.

If unable to observe the dressing change due to the dressing protocol, observe the area surrounding the ulcer(s). For ulcers with dressings that are not scheduled to be changed, the surveyor may request that the dressing be removed to observe the wound and surrounding area if other information suggests a possible treatment or assessment problem.

If the resident expresses (or appears to be in) pain related to the ulcer or treatment, determine if the facility:

• Assessed for pain related to the ulcer, addressed and monitored interventions for effectiveness; and/or
• Assessed and took preemptive measures for pain related to dressing changes or other treatments, such as debridement/irrigations, and monitored for effectiveness.

2. Resident/Staff Interviews

Interview the resident, family or responsible party to the degree possible to identify:

• Involvement in care plan, choices, goals, and if interventions reflect preferences;
• Awareness of approaches, such as pressure redistribution devices or equipment, turning/repositioning, weight shifting to prevent or address pressure ulcer(s);
• Presence of pain, if any, and how it is managed;

• If treatment(s) was refused, whether counseling on alternatives, consequences, and/or other interventions was offered; and
• Awareness of current or history of an ulcer(s). For the resident who has or has had a pressure ulcer, identify, as possible, whether acute illness, weight loss or other condition changes occurred prior to developing the ulcer.

Interview staff on various shifts to determine:
• Knowledge of prevention and treatment, including facility-specific guidelines/protocols and specific interventions for the resident;
• If nursing assistants know what, when, and to whom to report changes in skin condition; and
• Who monitors for the implementation of the care plan, changes in the skin, the development of pressure ulcers, and the frequency of review and evaluation of an ulcer.

3. Record Review

Assessment

Review the RAI and other documents such as physician orders, progress notes, nurses' notes, pharmacy or dietary notes regarding the assessment of the resident's overall condition, risk factors and presence of a pressure ulcer(s) to determine if the facility identified the resident at risk and evaluated the factors placing the resident at risk:
• For a resident who was admitted with an ulcer or who developed one within 1 to 2 days, review the admission documentation regarding the wound site and characteristics at the time of admission, the possibility of underlying tissue damage because of immobility or illness prior to admission, skin condition on or within a day of admission, history of impaired nutrition; and history of previous pressure ulcers; and
• For a resident who subsequently developed or has an existing pressure ulcer, review documentation regarding the wound site, characteristics, progress and complications including reassessment if there were no signs of progression towards healing within 2 to 4 weeks.

In considering the appropriateness of a facility's response to the presence, progression, or deterioration of a pressure ulcer, take into account the resident's condition, complications, time needed to determine the effectiveness of a treatment, and the facility's efforts, where possible, to remove, modify, or stabilize the risk factors and underlying causal factors.

Care Plan

For the resident at risk for developing or who has a pressure ulcer, determine if the facility developed an individualized care plan that addresses prevention, care and treatment of any existing pressure ulcers, including specific interventions, measurable objectives and approximate time frames.

If the facility's care of a specific resident refers to a treatment protocol that contains details of the treatment regimen, the care plan should refer to that protocol. The care plan should clarify any major deviations from, or revisions to, that protocol in a specific resident.

A specific care plan intervention for risk of pressure ulcers is not needed if other components of the care plan address related risks adequately. For example, the risk of skin breakdown posed by fecal/urinary incontinence might be addressed in that part of

the care plan that deals with incontinence management.
If the resident refuses or resists staff interventions to reduce risk or treat existing pressure ulcers, determine if the care plan reflects efforts to seek alternatives to address the needs identified in the assessment.

Revision of the Care Plan

Determine if the staff have been monitoring the resident's response to interventions for prevention and/or treatment and have evaluated and revised the care plan based on the resident's response, outcomes, and needs. Review the record and interview staff for information and/or evidence that:

• Continuing the current approaches meets the resident's needs, if the resident has experienced recurring pressure ulcers or lack of progression toward healing and staff did not revise the care plan; and

• The care plan was revised to modify the prevention strategies and to address the presence and treatment of a newly developed pressure ulcer, for the resident who acquired a new ulcer.

4. Interviews with Health Care Practitioners and Professionals

If the interventions defined or care provided appear not to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. Depending on the issue, ask about:

• How it was determined that chosen interventions were appropriate;
• Risks identified for which there were no interventions;
• Changes in condition that may justify additional or different interventions; or
• How they validated the effectiveness of current interventions.

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F314)

The pressure ulcer requirement has two aspects. The first aspect requires the facility to prevent the development of pressure ulcer(s) in a resident who is admitted without pressure ulcer(s), unless the development is clinically unavoidable. The second aspect requires the facility to provide necessary treatment and services to promote healing, prevent infection and prevent new ulcers from developing. A facility may have noncompliance
in either or both aspects of this requirement.

Criteria for Compliance

• Compliance with 42 CFR 483.25(c)(1), F314, Pressure Sore
o For a resident who developed a pressure ulcer after admission, the facility is in compliance with this requirement, if staff have:
• Recognized and assessed factors placing the resident at risk for developing a pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;
• Defined and implemented interventions for pressure ulcer prevention in accordance with resident needs, goals and recognized standards of practice;

• Monitored and evaluated the resident's response to preventive efforts; and
• Revised the approaches as appropriate.

If not, the development of the pressure ulcer is avoidable, cite at F314.

• Compliance with 42 CFR 483.25(c)(2), F314, Pressure Sore

o For a resident who was admitted with a pressure ulcer, who has a pressure ulcer that is not healing, or who is at risk of developing subsequent pressure ulcers, the facility is in compliance with this requirement if they:

• Recognized and assessed factors placing the resident at risk of developing a new pressure ulcer or experiencing non-healing or delayed healing of a current pressure ulcer, including specific conditions, causes and/or problems, needs and behaviors;
• Defined and implemented interventions for pressure ulcer prevention and treatment in accordance with resident needs, goals and recognized standards of practice;
• Addressed the potential for infection;
• Monitored and evaluated the resident's response to preventive efforts and treatment interventions; and
• Revised the approaches as appropriate.

If not, cite at F314.

Non-compliance for F314

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Non-compliance for F314 may include (but is not limited to) one or more of the following, including failure to:

• Accurately or consistently assess a resident's skin integrity on admission and as indicated thereafter;
• Identify a resident at risk of developing a pressure ulcer(s);
• Identify and address risk factors for developing a pressure ulcer, or explain adequately why they could not or should not do so;
• Implement preventive interventions in accord with the resident's need and current standards of practice;
• Provide clinical justification for the unavoidable development or non-healing/ delayed healing or deterioration of a pressure ulcer;
• Provide appropriate interventions, care and treatment to an existing pressure ulcer to minimize infections and to promote healing;
• Implement interventions for existing wounds;
• Notify the physician of the resident's condition or changes in the resident's wound(s);
• Adequately implement pertinent infection management practices in relation to wound care; and
• Identify or know how to apply relevant policies and procedures for pressure ulcer prevention and treatment.

Potential Tags for Additional Investigation

During the investigation of F314, the surveyor may have determined that concerns may also be present with related outcome, process and/or structure requirements. The surveyor is cautioned to investigate these related requirements before determining

whether non-compliance may be present. Some examples of related requirements that should be considered include the following:

- 42 CFR 483.10(b)(11)(i)(B)&(C), F157, Notification of Changes
  - Determine if staff notified the physician of significant changes in the resident's condition or failure of the treatment plan to prevent or heal pressure ulcers; or the resident's representative (if known) of significant changes in the resident's condition in relation to the development of a pressure ulcer or a change in the progression of healing of an existing pressure ulcer.
- 42 CFR 483.20(b)(1), F272, Comprehensive Assessments
  - Determine if the facility comprehensively assessed the resident's skin condition, including existing pressure ulcers, and resident-specific risk factors (including potential causative factors) for the development of a pressure ulcer or non-healing of the ulcer.
- 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans
  - Determine if the facility developed a care plan that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and current standards of practice and included measurable objectives and timetables, specific interventions/services to prevent the development of pressure ulcers and/or to treat existing pressures ulcers.
- 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
  - Determine if the care plan was periodically reviewed and revised as necessary to prevent the development of pressure ulcers and to promote the healing of existing pressure ulcers.
- 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
  - Determine if pressure ulcer care was provided in accordance with accepted professional standards.
- 42 CFR 483.25, F309, Quality of Care
  - Determine if staff identified and implemented appropriate measures for the management of pain as indicated as related to pressure ulcers and pressure ulcer treatment.
- 42 CFR 482.30(a), F353, Sufficient Staff
  - Determine if the facility had qualified staff in sufficient numbers to assure the resident was provided necessary care and services, based upon the comprehensive assessment and care plan, to prevent or treat pressure ulcers.
- 42 CFR 483.40(a)(1), F385, Physician Supervision
  - Determine if the physician has assessed and developed a treatment regimen relevant to preventing or healing a pressure ulcer and responded appropriately to the notice of changes in condition.
- 42 CFR 483.75(i)(2), F501, Medical Director
  - Determine whether the medical director assisted the facility in the development and implementation of policies and procedures for pressure ulcer prevention and treatment, and that these are based on current standards of practice; and whether the medical director interacts with the physician supervising the care of the resident if requested by the facility to

intervene on behalf of the resident with a pressure ulcer(s).

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified the deficient practices that demonstrate that the facility failed to provide care and treatment to prevent or treat pressure ulcers and that non-compliance exists, the team must determine the severity of the deficient practice(s) and the resultant harm or potential for harm to the resident. The key elements for severity determination for F314 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F314 may include but is not limited to:

• Potential for development of, occurrence or recurrence of (an) avoidable pressure ulcer(s);

• Complications such as sepsis or pain related to the presence of avoidable pressure ulcer(s); and/or

• Pressure ulcers that fail to improve as anticipated or develop complications such as sepsis or pain because of the lack of appropriate treatment and care.

2. Degree of harm (actual or potential) related to the non-compliance

Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise or discomfort; and

• If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise or discomfort to occur to the resident.

3. The immediacy of correction required

Determine whether the non-compliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F314. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability and severity. (Follow the guidance in Appendix Q.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's non-compliance:

• With one or more requirements of participation has caused/resulted in, or is likely to cause, serious injury, harm, impairment or death to a resident; and

• Requires immediate correction as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of possible avoidable negative outcomes may include:

• Development of avoidable Stage IV pressure ulcer(s): As a result of the facility's non-compliance, permanent tissue damage (whether or not healing occurs) has compromised the resident, increasing the potential for serious complications including osteomyelitits and sepsis.

• Admitted with a Stage IV pressure ulcer(s) that has shown no signs of healing or shows signs of deterioration: As a result of the facility's non-compliance, a Stage

IV pressure ulcer has shown signs of deterioration or a failure to progress towards healing with an increased potential for serious complications including osteomyelitis and sepsis.

• Stage III or IV pressure ulcers with associated soft tissue or systemic infection: As a result of the facility's failure to assess or treat a resident with an infectious complication of a pressure ulcer. (See discussion in guidelines and definitions that distinguishes colonization from infection.)

• Extensive failure in multiple areas of pressure ulcer care: As a result of the facility's extensive noncompliance in multiple areas of pressure ulcer care, the resident developed recurrent and/or multiple, avoidable Stage III or Stage IV pressure ulcer(s).

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable negative outcomes may include but are not limited to:

• **The development of avoidable Stage III pressure ulcer(s):** As a result of the facility's non-compliance, Stage III pressure ulcers occurred, which are open wounds in which damage has occurred into the subcutaneous level and may be painful.

• **The development of recurrent or multiple avoidable Stage II pressure ulcer(s):** As a result of the facility's non-compliance, the resident developed multiple and/or recurrent avoidable Stage II ulcers.

• **Failure to implement the comprehensive care plan for a resident who has a pressure ulcer**: As a result of a facility's failure to implement a portion of an existing plan related to pressure ulcer care, such as failure to provide for pressure redistribution, or inappropriate treatment/dressing changes, a wound increased in size or failed to progress towards healing as anticipated, or the resident experienced untreated pain.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of avoidable negative outcomes may include but are not limited to:

• **The development of a single avoidable Stage II pressure ulcer that is receiving appropriate treatment:** As a result of the facility's non-compliance, a resident developed an avoidable Stage II pressure ulcer.

• **The development of an avoidable Stage I pressure ulcer**: As a result of the

facility’s non-compliance, a resident developed an avoidable Stage I pressure ulcer.

• **Failure to implement an element of the care plan for a resident who has a pressure ulcer however, there has been no evidence of decline or failure to heal.**

• **Failure to recognize or address the potential for developing a pressure ulcer:** As a result of the facility’s non-compliance, staff failed to identify the risks, develop a plan of care and/or consistently implement a plan that has been developed to prevent pressure ulcers.

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services to prevent pressure ulcers or heal existing pressure ulcers is more than minimal harm. Therefore, Severity Level 1 doesn't apply for this regulatory requirement.

F315
§483.25(d) Urinary Incontinence

Based on the resident's comprehensive assessment, the facility must ensure that --
§483.25(d) (1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and
§483.25(d) (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

INTENT: (F315) 42 CFR 483.25 (d) (1) and (2) Urinary Incontinence and Catheters

The intent of this requirement is to ensure that:

• Each resident who is incontinent of urine is identified, assessed and provided appropriate treatment and services to achieve or maintain as much normal urinary function as possible;
• An indwelling catheter is not used unless there is valid medical justification;
• An indwelling catheter for which continuing use is not medically justified is discontinued as soon as clinically warranted;
• Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the catheter; and
• A resident, with or without a catheter, receives the appropriate care and services to prevent infections to the extent possible.

DEFINITIONS

Definitions are provided to clarify clinical terms related to evaluation and treatment of urinary incontinence and catheter use.

• "Bacteremia" is the presence of bacteria in the bloodstream.
• "Bacteriuria" is defined as the presence of bacteria in the urine.
• "Urinary Incontinence" is the involuntary loss or leakage of urine. There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:
o "Functional Incontinence" refers to loss of urine that occurs in residents whose urinary tract function is sufficiently intact that they should be able to maintain continence, but who cannot remain continent because of external factors (e.g., inability to utilize the toilet facilities in time);
o "Mixed Incontinence" is the combination of stress incontinence and urge incontinence;
o "Overflow Incontinence" is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended;
o "Stress Incontinence" (outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.;
o "Transient Incontinence" refers to temporary episodes of urinary incontinence that are reversible once the cause(s) of the episode(s) is (are) identified and treated; and

o "Urge Incontinence" (overactive bladder) is associated with detrusor muscle overactivity (excessive contraction of the smooth muscle in the wall of the urinary bladder resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full).

• "Urinary Retention" is the inability to completely empty the urinary bladder by micturition.

• "Urinary Tract Infection" (UTI) is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.

• "Urosepsis" refers to the systemic inflammatory response to infection (sepsis) that appears to originate from a urinary tract source. It may present with symptoms such as fever, hypotension, reduced urine output, or acute change in mental status.

INVESTIGATIVE PROTOCOL
URINARY CONTINENCE AND CATHETERS

Objectives

• To determine whether the initial insertion or continued use of an indwelling catheter is based upon clinical indication for use of a urinary catheter;

• To determine the adequacy of interventions to prevent, improve and/or manage urinary incontinence; and

• To determine whether appropriate treatment and services have been provided to prevent and/or treat UTIs.

Use

Use this protocol for a sampled resident with an indwelling urinary catheter or for a resident with urinary incontinence.

Procedures

Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. Staff are expected to assess and provide appropriate care from the day of admission, for residents with urinary incontinence or a condition that may contribute to incontinence or the presence of an indwelling urinary catheter (including newly admitted residents). Corroborate observations by interview and record review.

NOTE: Criteria established in this protocol provide general guidelines and best practices which should be considered when making a determination of compliance, and is not an exhaustive list of mandatory elements.

1. Observation

Observe whether staff consistently implemented care plan interventions across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan or from current standards of practice, as well as potential negative outcomes.

Observe whether staff make appropriate resident accommodations consistent with the

assessment, such as placing the call bell within reach and responding to the call bell, in relation to meeting toileting needs; maintaining a clear pathway and ready access to toilet facilities; providing (where indicated) elevated toilet seats, grab bars, adequate lighting, and assistance needed to use devices such as urinals, bedpans and commodes.
Observe whether assistance has been provided to try to prevent incontinence episodes, such as whether prompting, transfer, and/or stand-by assist to ambulate were provided as required for toileting.
For a resident who is on a program to restore continence or is on a prompted void or scheduled toileting program, note:
• The frequency of breakthrough or transient incontinence;
• How staff respond to the incontinence episodes; and
• Whether care is provided in accord with standards of practice (including infection control practices) and with respect for the resident's dignity.
For a resident who has been determined by clinical assessment to be unable to participate in a program to restore continence or in a scheduled toileting program and who requires care due to incontinence of urine, observe:
Whether the resident is on a scheduled check and change program; and
Whether staff check and change in a timely fashion.
For a resident who has experienced an incontinent episode, observe:
The condition of the pads/sheets/clothing (a delay in providing continence care may be indicated by brown rings/circles, saturated linens/clothing, odors, etc.);
The resident's physical condition (such as skin integrity, maceration, erythema, erosion);
The resident's psychosocial outcomes (such as embarrassment or expressions of humiliation, resignation, about being incontinent);
• Whether staff implemented appropriate hygiene measures (e.g., cleansing, rinsing, drying and applying protective moisture barriers or barrier films as indicated) to try to prevent skin breakdown from prolonged exposure of the skin to urine; and
Whether the staff response to incontinence episodes and the provision of care are consistent with standards of practice (including infection control practices) and with respect for the resident's dignity.
For a resident with an indwelling catheter, observe the delivery of care to evaluate:
• Whether staff use appropriate infection control practices regarding hand washing, catheter care, tubing, and the collection bag;
• Whether staff recognize and assess potential evidence of symptomatic UTI or other related changes in urine condition (such as onset of bloody urine, cloudiness, or oliguria, if present);
• How staff manage and assess urinary leakage from the point of catheter insertion to the bag, if present;
• If the resident has catheter-related pain, how staff assess and manage the pain; and
• What interventions (such as anchoring the catheter, avoiding excessive tugging on the catheter during transfer and care delivery) are being used to prevent inadvertent catheter removal or tissue injury from dislodging the catheter.
For a resident experiencing incontinence and who has an indwelling or intermittent catheter, observe whether the resident is provided and encouraged to take enough fluids

to meet the resident's hydration needs, as reflected in various measures of hydration status (approximately 30ml/kg/day or as indicated based on the resident's clinical condition). For issues regarding hydration, see Guidance at 42 CFR 483.25(j), F327.

2. Interviews

Interview the resident, family or responsible party to the degree possible to identify:

• Their involvement in care plan development including defining the approaches and goals, and whether interventions reflect preferences and choices;

• Their awareness of the existing continence program and how to use devices or equipment;

• If timely assistance is provided as needed for toileting needs, hydration and personal hygiene and if continence care and/or catheter care is provided according to the care plan;

• If the resident comprehends and applies information and instructions to help improve or maintain continence (where cognition permits);

• Presence of urinary tract-related pain, including causes and management;

• If interventions were refused, whether consequences and/or other alternative approaches were presented and discussed; and

• Awareness of any current UTI, history of UTIs, or perineal skin problems.

If the resident has a skin problem that may be related to incontinence, or staff are not following the resident's care plan and continence/catheter care program, interview the nursing assistants to determine if they:

Are aware of, and understand, the interventions specific to this resident (such as the bladder or bowel restorative/management programs);

Have been trained and know how to handle catheters, tubing and drainage bags and other devices used during the provision of care; and

Know what, when, and to whom to report changes in status regarding bowel and bladder function, hydration status, urine characteristics, and complaints of urinary-related symptoms.

3. Record Review

Assessment and Evaluation. Review the RAI, the history and physical, and other information such as physician orders, progress notes, nurses' notes, pharmacist reports, lab reports and any flow sheets or forms the facility uses to document the resident's voiding history, including the assessment of the resident's overall condition, risk factors and information about the resident's continence status, rationale for using a catheter, environmental factors related to continence programs, and the resident's responses to catheter/continence services. Request staff assistance, if the information is not readily available.

Determine if the facility assessment is consistent with or corroborated by documentation within the record and comprehensively reflects the status of the resident for:

• Patterns of incontinent episodes, daily voiding patterns or prior routines;

• Fluid intake and hydration status;

• Risks or conditions that may affect urinary continence;

• Use of medications that may affect continence and impaired continence that could reflect adverse drug reactions;

• Type of incontinence (stress, urge, overflow, mixed, functional, or transient incontinence) and contributing factors;

• Environmental factors that might facilitate or impede the ability to maintain bladder continence, such as access to the toilet, call bell, type of clothing and/or continence products, ambulation devices (walkers, canes), use of restraints, side rails;
• Type and frequency of physical assistance necessary to facilitate toileting;
• Clinical rationale for use of an indwelling catheter;
• Alternatives to extended use of an indwelling catheter (if possible); and
• Evaluation of factors possibly contributing to chronically recurring or persistent UTIs.

Care Plan. If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the protocol must be available to the direct care staff, so that they may be familiar with it and use it. The care plan should clarify any significant deviations from such a protocol for a specific resident. If care plan interventions that address aspects of continence and skin care related to incontinence are integrated within the overall care plan, the interventions do not need to be repeated in a separate continence care plan.

Review the care plan to determine if the plan is based upon the goals, needs and strengths specific to the resident and reflects the comprehensive assessment. Determine if the plan:
• Identifies quantifiable, measurable objectives with time frames to be able to assess whether the objectives have been met;
• Identifies interventions specific enough to guide the provision of services and treatment (e.g., toilet within an hour prior to each meal and within 30 minutes after meals, or check for episodes of incontinence within 30 minutes after each meal or specific times based upon the assessment of voiding patterns);
• Is based upon resident choices and preferences;
• Promotes maintenance of resident dignity;
• Addresses potential psychosocial complications of incontinence or catheterization such as social withdrawal, embarrassment, humiliation, isolation, resignation;
• Includes a component to inform the resident and representative about the risks and benefits of catheter use, on continence management approaches, medications selected, etc.;
• Addresses measures to promote sufficient fluid intake, including alternatives such as food substitutes that have a high liquid content, if there is reduced fluid intake;
• Defines interventions to prevent skin breakdown from prolonged exposure to urine and stool;
• Identifies and addresses the potential impact on continence of medication and urinary tract stimulants or irritants (e.g., caffeine) in foods and beverages;
• Identifies approaches to minimize risk of infection (personal hygiene measures and catheter/tubing/bag care); and
• Defines environmental approaches and devices needed to promote independence in toileting, to maintain continence, and to maximize independent functioning.

For the resident who is not on a scheduled toileting program or a program to restore normal bladder function to the extent possible, determine if the care plan provides specific approaches for a check and change program.

For the resident who is on a scheduled toileting or restorative program (e.g., retraining, habit training, scheduled voiding, prompted voiding, toileting devices), determine

whether the care plan:
• Identifies the type of urinary incontinence and bases the program on the resident's voiding/elimination patterns; and
• Has been developed by considering the resident's medical/health condition, cognitive and functional ability to participate in a relevant continence program, and needed assistance.
For the resident with a catheter, determine whether the care plan:
• Defines the catheter, tubing and bag care, including indications, according to facility protocol, for changing the catheter, tubing or bag;
• Provides for assessment and removal of the indwelling catheter when no longer needed; and
• Establishes interventions to minimize catheter-related injury, pain, encrustation, excessive urethral tension, accidental removal, or obstruction of urine outflow.
Care Plan Revision. Determine if the resident's condition and effectiveness of the care plan interventions have been monitored and care plan revisions were made (or justifications for continuing the existing plan) based upon the following:
• The outcome and/or effects of goals and interventions;
• A decline or lack of improvement in continence status;
• Complications associated with catheter usage;
• Resident failure to comply with a continence program and alternative approaches that were offered to try to maintain or improve continence, including counseling regarding the potential consequences of not following the program;
• Change in condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems;
• Input by the resident and/or the responsible person; and
• An evaluation of the resident's level of participation in, and response to, the continence program.
4. Interviews with Health Care Practitioners and Professionals
If inconsistencies in care or potential negative outcomes have been identified, or care is not in accord with standards of practice, interview the nurse responsible for coordinating or overseeing the resident's care. Determine:
• How the staff monitor implementation of the care plan, changes in continence, skin condition, and the status of UTIs;
• If the resident resists toileting, how staff have been taught to respond;
• Types of interventions that have been attempted to promote continence (i.e., special clothing, devices, types and frequency of assistance, change in toileting schedule, environmental modifications);
• If the resident is not on a restorative program, how it was determined that the resident could not benefit from interventions such as a scheduled toileting program;
• For the resident on a program of toileting, whether the nursing staff can identify the programming applicable to the resident, and:
- The type of incontinence;
- The interventions to address that specific type;
- How it is determined that the schedule and program is effective

(i.e., how continence is maintained or if there has been a decline or

improvement in continence, how the program is revised to address the changes); and
- Whether the resident has any physical or cognitive limitations that influence potential improvement of his/her continence;

• For residents with urinary catheters, whether the nursing staff:
- Can provide appropriate justification for the use of the catheter;
- Can identify previous attempts made (and the results of the attempts) to remove a catheter; and
- Can identify a history of UTIs (if present), and interventions to try to prevent recurrence.

If the interventions defined or care provided do not appear to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. Depending on the issue, ask about:

• How it was determined that the chosen interventions were appropriate;
• Risks identified for which there were no interventions;
• Changes in condition that may justify additional or different interventions; or how they validated the effectiveness of current interventions; and
• How they monitor the approaches to continence programs (e.g., policies/procedures, staffing requirements, how staff identify problems, assess the toileting pattern of the resident, develop and implement continence-related action plans, how staff monitor and evaluate resident's responses, etc.).

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F315)

The urinary incontinence requirement has three aspects. The first aspect requires that a resident who does not have an indwelling urinary catheter does not have one inserted unless the resident's clinical condition demonstrates that it was necessary. The second aspect requires the facility to provide appropriate treatment and services to prevent urinary tract infections; and the third is that the facility attempt to assist the resident to restore as much normal bladder function as possible.

Criteria for Compliance

• Compliance with 42 CFR 483.25(d)(1) and (2), F315, Urinary Incontinence
- For a resident who was admitted with an indwelling urinary catheter or who had one placed after admission, the facility is in compliance with this requirement, if staff have:
  - Recognized and assessed factors affecting the resident's urinary function and identified the medical justification for the use of an indwelling urinary catheter;
  - Defined and implemented pertinent interventions to try to minimize complications from an indwelling urinary catheter, and to remove it if clinically indicated, consistent with resident conditions, goals, and recognized standards of practice;
  - Monitored and evaluated the resident's response to interventions;

and
- Revised the approaches as appropriate.

If not, the use of an indwelling urinary catheter is not medically justified, and/or the ongoing treatment and services for catheter care were not provided consistent with the resident's needs. Cite F315.

o For a resident who is incontinent of urine, the facility is in compliance with this requirement if they:
- Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
- Defined and implemented interventions to address correctable underlying causes of urinary incontinence and to try to minimize the occurrence of symptomatic urinary tract infections in accordance with resident needs, goals, and recognized standards of practice;
- Monitored and evaluated the resident's response to preventive efforts and treatment interventions; and
- Revised the approaches as appropriate.

If not, the facility is not in compliance with the requirement to assist the resident to maintain or improve the continence status, and/or prevent the decline of the condition of urinary incontinence for the resident. Cite F315.

o For a resident who has or has had a symptomatic urinary tract infection, the facility is in compliance with this requirement if they have:
- Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
- Defined and implemented interventions to try to minimize the occurrence of symptomatic urinary tract infections and to address correctable underlying causes, in accordance with resident needs, goals, and recognized standards of practice;
- Monitored and evaluated the resident's responses to preventive efforts and treatment interventions; and
- Revised the approaches as appropriate.

If not, the development of a symptomatic urinary tract infection, and/or decline of the resident with one, was not consistent with the identified needs of the resident. Cite F315.

Noncompliance for F315

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F315 may include (but is not limited to) one or more of the following, including failure to:

• Provide care and treatment to prevent incontinence and/or improve urinary continence and restore as much normal bladder function as possible;

• Provide medical justification for the use of a catheter or provide services for a resident with a urinary catheter;

• Assess, prevent (to the extent possible) and treat a symptomatic urinary tract infection (as indicated by the resident's choices, clinical condition and physician treatment plan);

• Accurately or consistently assess a resident's continence status on admission and as indicated thereafter;
• Identify and address risk factors for developing urinary incontinence;
• Implement interventions (such as bladder rehabilitative programs) to try to improve bladder function or prevent urinary incontinence, consistent with the resident's assessed need and current standards of practice;
• Provide clinical justification for developing urinary incontinence or for the failure of existing urinary incontinence to improve;
• Identify and manage symptomatic urinary tract infections, or explain adequately why they could or should not do so;
• Implement approaches to manage an indwelling urinary catheter based upon standards of practice, including infection control procedures;
• Identify and apply relevant policies and procedures to manage urinary incontinence, urinary catheters and/or urinary tract infections;
• Notify the physician of the resident's condition or changes in the resident's continence status or development of symptoms that may represent a symptomatic UTI (in contrast to asymptomatic bacteriuria).

Potential Tags for Additional Investigation

During the investigation of 42 CFR 483.25(d)(1) and (2), the surveyor may have identified concerns related to outcome, process and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process and/or structure requirements that should be considered:

• 42 CFR 483.10(b)(11), F157, Notification of Changes
  o Determine if staff notified the physician of significant changes in the resident's continence, catheter usage, or the development, treatment and/or change in symptomatic UTIs; or notified the resident or resident's representative (where one exists) of significant changes as noted above.
• 42 CFR 483.15(a), F241, Dignity
  o Determine if staff provide continence care and/or catheter care to the resident in a manner that respects his/her dignity, strives to meet needs in a timely manner, monitors and helps the resident who cannot request assistance, and strives to minimize feelings of embarrassment, humiliation and/or isolation related to impaired continence.
• 42 CFR 483.20(b)(1), F272, Comprehensive Assessments
  o Determine if the facility comprehensively assessed the resident's continence status and resident-specific risk factors (including potential causes), and assessed for the use of continence-related devices, including an indwelling catheter.
• 42 CFR 483.20(k), F279, Comprehensive Care Plans
  o Determine if the facility developed a care plan (1) that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and with current standards of practice and (2) that includes measurable objectives, approximate timetables, specific interventions and/or services needed to prevent or address incontinence, provide catheter care; and to prevent UTIs to the extent possible.

• 42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision
o Determine if the care plan was reviewed and revised periodically, as necessary, related to preventing, managing, or improving incontinence, managing an indwelling urinary catheter, possible discontinuation of an indwelling catheter, and attempted prevention and management of UTIs.
• 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
o Determine if services and care were provided for urinary incontinence, catheter care and/or symptomatic UTIs in accordance with accepted professional standards.
• 42 CFR 483.25, F309, Quality of Care
o Determine if staff identified and implemented appropriate measures to address any pain related to the use of an indwelling urinary catheter or skin complications such as maceration, and to provide the necessary care and services in accordance with the comprehensive assessment plan of care.
• 42 CFR 483.25 (a)(3) F312, Quality of Care
o Determine if staff identified and implemented appropriate measures to provide good personal hygiene for the resident who cannot perform relevant activities of daily living, and who has been assessed as unable to achieve and/or restore normal bladder function.
• 42 CFR 483.40(a), F385, Physician Supervision
o Determine if the physician has evaluated and addressed, as indicated, medical issues related to preventing or managing urinary incontinence, catheter usage, and symptomatic UTIs.
• 42 CFR 483.65(b)(3), F444, Infection Control: Hand Washing
o Determine if staff wash their hands after providing incontinence care, and before and after providing catheter care.
• 42 CFR 483.75(f), F498, Proficiency of Nurse Aides
o Determine if nurse aides correctly deliver continence and catheter care, including practices to try to minimize skin breakdown, UTIs, catheter-related injuries, and dislodgement.
• 42 CFR 483.30(a), F353, Sufficient Staff
o Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services on a 24-hour basis, based upon the comprehensive assessment and care plan, to prevent, manage and/or improve urinary incontinence where possible.
• 42 CFR 483.75(i)(2), F501, Medical Director
o Determine whether the medical director, in collaboration with the facility and based on current standards of practice, has developed policies and procedures for the prevention and management of urinary incontinence, for catheter care, and for the identification and management of symptomatic urinary tract infections; and whether the medical director interacts, if requested by the facility, with the physician supervising the care of the resident related to the management of urinary incontinence, catheter or infection issues.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F315 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F315 may include, but is not limited to:

• Development, recurrence, persistence, or increasing frequency of urinary incontinence, which is not the result of underlying clinical conditions;

• Complications such as urosepsis or urethral injury related to the presence of an indwelling urinary catheter that is not clinically justified;

• Significant changes in psychosocial functioning, such as isolation, withdrawal, or embarrassment, related to the presence of un-assessed or unmanaged urinary incontinence and/or a decline in continence, and/or the use of a urinary catheter without a clinically valid medical justification; and

• Complications such as skin breakdown that are related to the failure to manage urinary incontinence;

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and

• If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident; and

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F315. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Immediate Jeopardy.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

• Has allowed/caused/resulted in, or is likely to allow/cause /result in serious injury, harm, impairment, or death to a resident; and

• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of possible negative outcomes as a result of the facility's deficient practices may include:

• **Complications resulting from utilization of urinary appliance(s) without medical justification:** As a result of incorrect or unwarranted (i.e., not medically

indicated) utilization of a urinary catheter, pessary, etc., the resident experiences injury or trauma (e.g., urethral tear) that requires surgical intervention or repair.
• **Extensive failure in multiple areas of incontinence care and/or catheter management:** As a result of the facility's noncompliance in multiple areas of continence care or catheter management, the resident developed urosepsis with complications leading to prolonged decline or death.
NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.
Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy
Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.
Examples of avoidable negative outcomes may include, but are not limited to:
• **The development of a symptomatic UTI:** As a result of the facility's noncompliance, the resident developed a symptomatic UTI, without long term complications, associated with the use of an indwelling catheter for which there was no medical justification.
• **The failure to identify, assess and mange urinary retention:** As a result of the facility's noncompliance, the resident had persistent overflow incontinence and/or developed recurrent symptomatic UTIs.
• **The failure to provide appropriate catheter care:** As a result of the facility's noncompliance, the catheter was improperly managed, resulting in catheterrelated pain, bleeding, urethral tears or urethral erosion.
• **Medically unjustified use of an indwelling catheter with complications:** As a result of the facility's noncompliance, a resident who was admitted with a urinary catheter had the catheter remain for an extended period of time without a valid medical justification for its continued use, or a urinary catheter was inserted after the resident was in the facility and used for an extended time without medical justification, during which the resident experienced significant complications such as recurrent symptomatic UTIs.
• **Decline or failure to improve continence status:** As a result of the facility's failure to assess and/or re-assess the resident's continence status, utilize sufficient staffing to implement continence programs and provide other related services based on the resident's assessed needs, and/or to evaluate the possible adverse effects of medications on continence status, the resident failed to maintain or improve continence status.
• **Complications due to urinary incontinence:** As a result of the facility's failure to provide care and services to a resident who is incontinent of urine, in accordance with resident need and accepted standards of practice, the resident developed skin maceration and/or erosion or declined to attend or participate in social situations (withdrawal) due to embarrassment or humiliation related to unmanaged urinary incontinence.
NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of potentially avoidable negative outcomes may include, but are not limited to:

• **Medically unjustified use of an indwelling catheter:** As a result of the facility's noncompliance, the resident has the potential for experiencing complications, such as symptomatic UTIs, bladder stones, pain, etc.

• **Complications associated with inadequate care and services for an indwelling catheter:** As a result of the facility's noncompliance, the resident has developed potentially preventable non-life-threatening problems related to the catheter, such as leaking of urine due to blockage of urine outflow, with or without skin maceration and/or dermatitis.

• **Potential for decline or complications:** As a result of the facility's failure to consistently implement a scheduled voiding program defined in accordance with the assessed needs, the resident experiences repeated episodes of incontinence but has not demonstrated a decline or developed complications.

Severity Level 1: No actual harm with potential for minimal harm

The failures of the facility to provide appropriate care and services to improve continence, manage indwelling catheters, and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

SELF SURVEY MODULE
483.25 (h) ACCIDENTS

REGULATION:
F323
(Rev. 27; Issued: 08-17-07; Effective/Implementation: 08-17-07)
§483.25(h) Accidents.
The facility must ensure that –
(1) The resident environment remains as free from accident hazards as is possible; and
(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

INTENT: 42 CFR 483.25(H) (1) AND (2) ACCIDENTS AND SUPERVISION
The intent of this requirement is to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents. This includes:
• Identifying hazard(s) and risk(s);
• Evaluating and analyzing hazard(s) and risk(s);
• Implementing interventions to reduce hazard(s) and risk(s); and
• Monitoring for effectiveness and modifying interventions when necessary.

DEFINITIONS
Definitions are provided to clarify terms related to providing supervision and other interventions to prevent accidents.
• "Accident" refers to any unexpected or unintentional incident, which may result in injury or illness to a resident. This does not include adverse outcomes that are a direct consequence of treatment or care that is provided in accordance with current standards of practice (e.g., drug side effects or reaction).
o "Avoidable Accident" means that an accident occurred because the facility failed to:
- Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and/or
- Evaluate/analyze the hazards and risks; and/or
- Implement interventions, including adequate supervision, consistent with a resident's needs, goals, plan of care, and current standards of practice in order to reduce the risk of an accident; and/or
- Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.
o "Unavoidable Accident" means that an accident occurred despite facility efforts to:
- Identify environmental hazards and individual resident risk of an accident, including the need for supervision; and
- Evaluate/analyze the hazards and risks; and
- Implement interventions, including adequate supervision,

consistent with the resident's needs, goals, plan of care, and current standards of practice in order to reduce the risk of an accident; and
- Monitor the effectiveness of the interventions and modify the interventions as necessary, in accordance with current standards of practice.

• "Assistance Device" or "Assistive Device" refers to any item (e.g., fixtures such as handrails, grab bars, and devices/equipment such as transfer lifts, canes, and wheelchairs, etc.) that is used by, or in the care of a resident to promote, supplement, or enhance the resident's function and/or safety.

NOTE: The currently accepted nomenclature refers to "assistive devices." Although the term "assistance devices" is used in the regulation, the Guidance provided in this document will refer to "assistive devices."

• "Environment" refers to the resident environment. (See definition for "resident environment.")

• "Fall" refers to unintentionally coming to rest on the ground, floor, or other lower level, but not as a result of an overwhelming external force (e.g., resident pushes another resident). An episode where a resident lost his/her balance and would have fallen, if not for staff intervention, is considered a fall. A fall without injury is still a fall. Unless there is evidence suggesting otherwise, when a resident is found on the floor, a fall is considered to have occurred.[1]

• "Hazards" refer to elements of the resident environment that have the potential to cause injury or illness.

o "Hazards over which the facility has control" are those hazards in the resident environment where reasonable efforts by the facility could influence the risk for resulting injury or illness.

o "Free of accident hazards as is possible" refers to being free of accident hazards over which the facility has control.

• "Resident environment" includes the physical surroundings to which the resident has access (e.g., room, unit, common use areas, and facility grounds, etc.).

• "Risk" refers to any external factor or characteristic of an individual resident that influences the likelihood of an accident.

• "Supervision/Adequate Supervision" refers to an intervention and means of mitigating the risk of an accident. Facilities are obligated to provide adequate supervision to prevent accidents. Adequate supervision is defined by the type and frequency of supervision, based on the individual resident's assessed needs and identified hazards in the resident environment. Adequate supervision may vary from resident to resident and from time to time for the same resident.

INVESTIGATIVE PROTOCOL
ACCIDENTS AND SUPERVISION

Objectives

• To determine if the facility has identified hazard(s) present in the resident environment and the individual resident's risks for an avoidable accident posed by those hazards;

• To determine if a resident accident was avoidable or unavoidable;

• To evaluate whether the facility provides an environment that is as free as possible of hazards over which the facility has control, and minimizes the potential for harm; and
• To determine if the facility provides adequate supervision and assistive devices to prevent avoidable accidents.

Use

Use this protocol:
• For a sampled resident who is at risk for, or who has a history of accidents, falls, or unsafe wandering/elopement, to determine if the facility provided care and services, including assistive devices as necessary, to prevent avoidable accidents and to reduce the resident's risk to the extent possible;
• For a sampled resident who is at risk for accidents or who creates a risk to others, to determine if the facility has provided adequate supervision; and
• For identified hazards/risks, to determine if there are facility practices in place to identify, evaluate and analyze hazards/risks; implement interventions to reduce or eliminate the hazards/risks, to the extent possible; and monitor the effectiveness of the interventions.

Procedures

Observe the general environment and sampled resident environment. For a sampled resident, briefly review the assessment and plan of care to determine whether the facility identified resident risks and implemented interventions as necessary to guide observations during the investigation. For a newly admitted resident at risk for avoidable accidents, determine if the staff assessed and provided appropriate care from the day of admission. Corroborate observations through interview and record review.

1. Observation

The survey team should make observations and investigate potential hazards that may be encountered throughout the survey. The existence of hazards may indicate a more serious problem; for example, that the organization lacks an effective system to identify and correct the problem independently. The previous discussion of specific common hazards guides surveyors to look for items indicating a failure or absence of an organization's systems and processes to enable safety.

During observation of the facility, the survey team may see individual residents who are smoking tobacco products. Whether or not these residents are part of the sample, the issue of facility fires is important enough that the survey team should determine if the situation is hazardous, requiring further investigation.

Observe the environment for the presence of potential/actual hazards including, but not limited to, the following:
• Accessibility of chemicals, toxics or other hazards such as housekeeping chemicals and supplies, medications, sharp utensils/tools, and cigarette lighters/smoking materials;
• Environmental conditions such as unstable or slippery floor surfaces, loose hand rails, excessive water temperatures, electrical hazards, insufficient or excessive light (glare), arrangement of living spaces, obstacles in corridors, unsupervised access into or egress out of the facility, low or loose toilet seats, defective or nonfunctioning
beds, or malfunctioning wheelchair brakes;

• Staff responses to verbal calls for help and alarms such as door, personal, and equipment alarms, and call bells;
• Assistive devices/equipment (e.g., mobility devices, lifts and transfer aids, bed rails, call lights, physical restraints, pumps, belts) that are defective; not used properly or according to manufacturer's specifications; disabled or removed; not provided or do not meet the resident's needs (poor fit or not adapted); and/or used without adequate supervision, in relation to the facility's assessment of the resident; and/or
• Staff response to potential/actual hazard(s) (e.g., cleaning up spilled liquids in a resident area, keeping residents away from the hazard).
For a sampled resident at risk, observe whether staff implement the care plan consistently over time and across various shifts. Observe how staff respond to any identified resident hazards. Observe how staff supervise the resident, such as during transfers and/or meals, and if caregivers have removed or modified observed hazards. During observations of the interventions, follow up on deviations from the plan of care, as well as potential negative outcomes.
For a resident who smokes, the facility's determination regarding the resident's abilities and capabilities would indicate whether supervision is required. If the resident is found to need supervision for smoking, this information is included in the resident's plan of care. Observe sampled resident(s) in the facility's designated smoking area. If the resident's care plan states supervision is required while smoking, confirm that supervision is provided. For others, note any concerns such as difficulty holding or lighting a cigarette or burned areas in clothing that may indicate the need for supervision.
Observe the resident to determine how the resident's risk influences his/her vulnerability to the observed potential hazard(s) and potential for an accident. Evaluate how the resident's risks relate to the observed potential hazards such as:
• The resident's access to the hazard and the ability to react appropriately; and/or
• The adequacy of the supervision provided for the resident who has been assessed to need supervision in relation to the identified potential hazard(s).
2. Interview
Conduct interviews to determine the relationship between the resident's risk and hazards. Interview the resident, family, and/or responsible party to the degree possible to identify:
• If the resident and/or responsible party reported, or helped identify the resident's risks for an accident and significant hazards in the resident's environment;
• If the resident and/or responsible party was aware of or identified a potential hazard for other residents;
• If the resident and/or responsible party reported a hazard or potential risk to staff; and
• How and when staff responded to a hazard once it was identified.
Interview staff to determine:
• If they were aware of planned interventions to reduce a resident's risk for an avoidable accident;
• If they reported potential resident risks or environmental hazards to the supervisor or others according to facility policy;
• If they acted to correct an immediate hazard, such as spilled liquids; and

• If they are aware of, and follow facility procedures correctly to remove or reduce hazards.

3. Record Review

Assessment and Evaluation: Review the RAI and other documents such as progress notes, physician orders, and nurses' and consultants' notes regarding the assessment of the resident's overall condition and risk factors to determine if the facility identified the resident's risk for avoidable accidents, evaluated and analyzed any risks, implemented interventions to try to prevent accidents and reduce the resident's risks, and monitored and modified interventions as necessary.

Determine if the facility assessment is consistent with or corroborated by documentation within the record and reflects the status of the resident for:

• Behavior such as unsafe wandering, elopement, ingesting nonfood items, altercations with others;
• Hearing, visual, and sensory impairments;
• Impaired physical functioning, balance, or gait problems;
• Diagnoses that could relate to safety awareness and safe practices, such as Alzheimer's and other dementias, arthritis, Parkinson's disease, seizure disorder, osteoporosis, cardiovascular/cerebrovascular diseases, depression/psychosis;
• Symptoms/conditions that could affect safety risk, such as vertigo, postural hypotension, or acute illness;
• Use of physical restraints and/or other devices that might limit movement;
• Medications that could affect function, level of consciousness, gait, balance, visual acuity, or cognitive ability, use such as antidepressants, anticholinergic medications, anti-hypertensives, diuretics, psychotropic medications, or initiation of new medication therapy; and
• History of falls.

Plan of Care: Review the plan of care to determine if the facility developed interventions based on the resident's risks to try to prevent avoidable accidents, and if the plan was modified as needed based on the response, outcomes, and needs of the resident.

If the resident has had an accident, review the record to determine if the accident is:

• The result of an order not being followed; and/or
• A care need not being addressed; and/or
• A plan of care not being implemented.

In addition, determine if the facility (1) investigated the cause of the accident and (2) if indicated, implemented revised interventions to prevent additional avoidable accidents.

Plan of Care Revision: Determine if the facility has monitored a resident's condition and the effectiveness of the plan of care interventions and has made revisions (or has documented justification for continuing the existing plan) based upon the following:

• The outcome and/or effects of goals and interventions;
• Resident failure to comply with the plan of care and interventions;
• Input by the resident and/or the responsible person; and
• Changes in condition such as the ability to make decisions, cognition, functional impairment, or changes in the medication regimen.

4. Review of Facility Practices

The presence or absence of effective facility practices to provide a safe resident environment can influence the likelihood of an accident occurring and subsequent harm

to a resident(s). Hazards that have been allowed to exist for a long time, or a facility history of similar problems, could indicate inadequate or ineffective facility practices. If, during the tour, surveyors identify care delivery, hazards or potential hazards, or a history of resident accidents, the survey team should share the findings with the entire team and determine who will lead the investigation of the facility's systems for identifying, evaluating and preventing avoidable accidents or hazards. Review of facility practices may involve a review of policies and procedures, staffing, staff training, and equipment manufacturer's information, as well as interviews with staff and management. If there is a pattern of accidents involving one or more residents, determine how the facility evaluates its responses to the accidents. Determine if the facility ensured that the resident environment remained as free of accident hazards as possible and if each resident received adequate supervision and assistive devices to try to prevent accidents by:

• Identifying potential hazards and risks (may require various strategies to gather such information);
• Evaluating and analyzing the information gathered to identify the underlying causes of the hazard and/or risk;
• Implementing interventions that addressed the causes and prioritized actions based on severity of the hazard and immediacy of the risk; and
• Monitoring implementation of interventions and determining if modification is needed.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation

The requirements at 42 CFR 483.25(h)(1) and (2) have three aspects. The first aspect requires that a resident's environment remains as free of accident hazards as possible; the second aspect requires that the facility provide adequate supervision; and the third is that the facility provides assistive devices to prevent accidents.

Criteria for Compliance

The facility's responsibility to accommodate individual needs and preferences and abide by the resident's right to choice and self-determination must be balanced against compliance with F323 to protect the resident. Documentation regarding the resident's choices will assist the survey team in making compliance decisions.

NOTE: It is important to remember that not all accidents in a facility, regardless of outcome to a resident, are necessarily due to facility noncompliance. A resident can sustain bodily injury as a result of an accident over which the facility had no control (i.e., an unavoidable accident). The survey team needs to review the situation that led to the injury or potential for injury, as well as the facility practices, and resident's rights, preferences, and choices, to determine if the potential or negative outcome was avoidable or unavoidable.

Compliance with 42 CFR 483.25(h)(1) and (2), F323, Accidents and Supervision

For the resident who has had an accident or was assessed at risk for an avoidable accident, the facility is in compliance with this requirement, if staff have:

• Identified hazards and risk of an avoidable accident based on the facility's assessment of the resident environment and the resident, including the need for supervision and/or assistive devices;
• Evaluated/analyzed the hazards and risks;

• Implemented interventions, including adequate supervision and/or assistive devices, to reduce the risks of an accident that were consistent with a resident's needs, goals, plan of care, and current standards of practice;
• Provided assistive devices consistent with a resident's needs;
• Properly deployed and maintained resident specific equipment (e.g., lifts, canes, wheelchairs, walkers);
• Provided a safe environment, such as by monitoring chemicals, wet floors, cords and other equipment;
• Operated equipment in accordance with manufacturer's recommendations and resident need;
• Provided and maintain a secure environment (e.g., resident room, unit, common use areas, stairs and windows, facility grounds, etc.) to prevent negative outcomes (e.g., prevent falling/tumbling down stairs or jumping from windows or eloping through exit doors) for residents who exhibit unsafe wandering and/or elopement behavior (regardless of whether ambulatory, in wheelchair or using walker); and
• Monitored the effectiveness of the interventions and modified the interventions as necessary, in accordance with current standards of practice.
If not, cite F323.
Noncompliance for F323
After completing the investigation, determine whether or not compliance with the regulation exists. Noncompliance for F323 may include, but is not limited to, one or more of the following failures to:
• Provide each resident an environment that is as free as possible from hazards over which the facility has control, such as assuring safe storage of toxic chemicals and medications, and safe use of equipment and electrical appliances;
• Provide adequate supervision for a resident who has exhibited unsafe wandering and/or has a risk of and/or a history of elopement;
• Identify and correct hazards such as non-functional alarms or call systems, disabled locks, fire doors that have been propped open, irregular walking surfaces, inadequate lighting or unsafe water temperatures;
• Supervise and monitor a resident who smokes and whose comprehensive assessment and plan of care indicates a need for supervision;
• Provide assistive devices and/or appropriate training for the use of assistive devices, based upon the assessed needs of the resident;
• Monitor for defective or disabled equipment, such as pumps, ventilators or other equipment, or the improper use of assistive devices;
• Assess, develop interventions, and/or revise the plan of care for a resident who has experienced falls, or who is identified as having risk factors for falling; and
• Assess, develop interventions, and/or revise the plan of care for a resident who has exhibited or has a risk for unsafe wandering or elopement.

Potential Tags for Additional Investigation

During the investigation of 42 CFR 483.25(h)(1) and (2), the surveyor may have identified concerns related to outcome, process, and/or structure requirements. The surveyor should investigate these requirements before determining whether noncompliance may be present. The following are examples of related outcome, process,

and/or structure requirements that should be considered:

- 42 CFR 483.13(a), F221, Restraints
  - Determine if staff attempted alternative approaches prior to the use of a restraint and if a medical indication for its use is present.
- 42 CFR 483.13(b), F223, Abuse
  - Determine if the resident was free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.
- 42 CFR 483.20(b)(1), F272, Comprehensive Assessments
  - Determine if the facility comprehensively assessed resident-specific risk factors (including potential causes) and assessed the need for and use of assistive devices.
- 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans
  - Determine if the facility developed a plan of care based on the comprehensive resident assessment consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and with current standards of practice, and that includes measurable objectives and approximate timetables, specific interventions and/or services including necessary supervision and/or any assistive devices needed to prevent accidents to the extent possible.
- 42 CFR 483.20(k)(2), F280, Comprehensive Care Plan Revision
  - Determine if the plan of care was reviewed and revised periodically, as necessary, related to preventing accidents, supervision required, and the use of assistive devices.
- 42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards
  - Determine if services and care were provided for the use of assistive devices, supervision, and prevention of accidents in accordance with accepted professional standards.
- 42 CFR 483.30(a), F353, Sufficient Staff
  - Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services, including supervision, based upon the comprehensive assessment and care plan, to prevent accidents, as possible.
- 42 CFR 483.75(o), F520, Quality Assessment and Assurance
  - Determine whether the quality assessment and assurance committee has identified issues, and developed and implemented appropriate plans of action to correct identified quality deficiencies in relation to hazards, accident prevention, and supervision of residents.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the survey team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that noncompliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F323 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of presence of environmental hazards, lack of adequate supervision to prevent accidents, or failure to provide assistive devices to prevent accidents. Actual or

potential harm/negative outcome for F323 may include, but is not limited to:
• Injuries sustained from falls and/or unsafe wandering/elopement;
• Resident-to-resident altercations;
• Thermal burns from spills/immersion of hot water/liquids;
• Falls due to environmental hazards;
• Ingestion of chemical substances; and
• Burns related to smoking materials.
2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility noncompliance caused, resulted in, allowed, or contributed to the actual or potential for harm.
• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
• If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident.
3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.
The survey team must evaluate the harm or potential for harm based upon the following levels of severity for Tag F323. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, **Guidelines for Determining Immediate Jeopardy**.)
Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety
Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:
• Has allowed, caused, or resulted in (or is likely to allow, cause, or result in) serious injury, harm, impairment, or death to a resident; and
• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventive or corrective measures.
NOTE: The death or transfer of a resident, who was harmed or injured as a result of facility noncompliance, does not always remove a finding of Immediate Jeopardy. The facility is required to implement specific actions to correct the noncompliance which allowed or caused the Immediate Jeopardy.
When considering Severity Level 4, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. Examples of negative outcomes that occurred or have the potential to occur as a result of the noncompliance might include the following:
• Esophageal damage due to ingestion of corrosive substances;
• Loss of consciousness related to head injuries;
• 3rd degree burn, or a 2nd degree burn covering a large surface area;
• Fracture or other injury that may require surgical intervention and results in significant decline in mental and/or physical functioning;
• Electric shock due to use of unsafe or improperly maintained equipment;
• Entrapment of body parts, such as limbs, head, neck, or chest that cause injury or death as a result of defective or improperly latched side rails or spaces within

side rails, between split rails, between rails and the mattress, between side rails and the bed frame, or spaces between side rails and the head or foot board of the bed;
• Entrapment of body parts, such as limbs, head, neck, or chest that causes or has the potential to cause serious injury, harm, impairment or death as a result of any manual method, physical or mechanical device, material, or equipment;
• Fall(s) that resulted in or had the potential to result in serious injury, impairment, harm or death (e.g. fracture or other injury that may require surgical intervention and/or results in significant decline in mental and/or physical functioning), and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s), that would have prevented the fall or limited the resident's injury; or
• Unsafe wandering and/or elopement that resulted in or had the potential to result in serious injury, impairment, harm or death (e.g., resident leaves facility or locked unit unnoticed and sustained or had potential to sustain serious injury, impairment, harm or death), and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s), that would have prevented or limited the resident's exposure to hazards.
NOTE: If Immediate Jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.
Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy
Severity Level 3 indicates noncompliance that results in actual harm and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.
When considering Severity Level 3, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. As a result of the noncompliance, a negative outcome occurred. Some examples of compromise include:
• Short-term disability;
• Pain that interfered with normal activities;
• 2nd degree burn;
• Fracture or other injury that may require surgical intervention and does not result in significant decline in mental and/or physical functioning;
• Medical evaluation was necessary, and treatment beyond first aid (e.g., sutures) was required;
• Fall(s) that resulted in actual harm (e.g., short-term disability; pain that interfered with normal activities; fracture or other injury that may require surgical intervention and does not result in significant decline in mental and/or physical functioning; or medical evaluation was necessary, and treatment beyond first aid (e.g., sutures) was required) and the facility had established measure(s) or practice(s) in place that limited the resident's potential to fall and limited the resident's injury and prevented the harm from rising to a level of immediate jeopardy; or
• Unsafe wandering and/or elopement that resulted in actual harm and the facility had established measure(s) or practice(s) in place that limited the resident's

exposure to hazards and prevented the harm from rising to a level of immediate jeopardy.

NOTE: Unsafe wandering or elopement that resulted in actual harm and the facility had no established measure(s) or practice(s), or ineffective measure(s) or practice(s) that would have prevented or limited the resident's exposure to hazards should be cited at Level 4, Immediate Jeopardy.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, evaluate whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Severity Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

When considering Severity Level 2, the survey team must have already determined noncompliance in the facility practices to provide a safe resident environment. As a result of the noncompliance, a negative outcome occurred, or the potential for a negative outcome exists, such as the following:

• Bruising, minor skin abrasions, and rashes;
• Pain that does not impair normal activities;
• 1st degree burn;
• Medical evaluation or consultation may or may not have been necessary, and treatment such as first aid may have been required;
• Fall(s) which resulted in no more than minimal harm (e.g., bruising or minor skin abrasions; pain that does not impair normal activities; or medical evaluation or consultation may or may not have been necessary, and/or treatment such as first aid may have been required) because the facility had additional established measure(s) or practice(s) that limited the resident's potential to fall or limited the injury or potential for injury; or
• Unsafe wandering and/or elopement, which resulted in no more than minimal harm because the facility had additional established measure(s) or practice(s) that limited the resident's exposure to hazards. For example, a resident with Alzheimer's disease left the locked unit and was quickly found unharmed on another unit, and the building was considered a safe environment, as there was no way for the resident to leave the building.

Severity Level 1 Considerations: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide a safe environment and adequate supervision places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

SELF SURVEY MODULE

425.25 (i) MALNOURISHMENT

TAG F325

REGULATION:

F325 Malnourishment

(1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.

INTENT:

The intent of this regulation is to assure that the resident maintains acceptable parameters of nutritional status, taking into account the resident's clinical condition or other appropriate intervention, when there is a nutritional problem.

DATA COLLECTION

OBSERVATION STRATEGIES:

Observe during entire time of survey and the entire facility

OBSERVATIONS:

a. Residents
b. Nursing assistants
c. Staff
d. Other
e. Residents' rooms and dining area
f. Possibly other areas of facility
g. Kitchen and prep

1. **RESIDENTS:**

a. General appearance: size, skin, status of teeth, gums, eyes, hair, mouth, lips, tongue, pallor, nails, alertness, physical abilities, abilities to feed self, chewing and swallowing ability.
b. Behavior problems: wandering, distractibility, mood and confusion

2. **DINING ROOM AND RESIDENT'S ROOM:**

Preparation of resident to consume meal: surveyor positioned to observe the feeding process and staff working with resident

a. Positioning:
1. Resident's room – chairs, table, overbed tables
2. Positioning of resident
b. Accessibility of food: Cartons opened, Cellophane wraps removed, Adaptive devices available, needed utensils, chairs, cups, plate with guard
c. Staff/resident interaction
1. Staff numbers
2. Assistance provided in dining room and resident's room
3. Staff approach to residents
4. Restorative feeding
d. Appropriate glasses, dentures, and hearing aids
e. Lighting, noise level
f. Diet card vs. what served; likes/dislikes/menus type of diet; substitutes available and/or offered
g. Food form appropriate, food presentation, color, and variety
h. Food identified by staff for resident

Identified for visually impaired residents especially juice, soup, coffee, tea
(injury) water
i. Condiments available? Supplement needed? Double portions?
j. Food allergies noted? Drug and food interactions? Served?
k. Thicken liquids needed, thickened appropriately
l. Percentage of meal consumption, food presentation, food form, frequency?
m. Supplements: timing and presentation to resident (if asleep, etc.)
n. Observe resident's room for personal supplies of food, families providing
"extra" foods that affect appetite, consumption.

3. **KITCHEN:**

a. Menu nutritionally complete and followed
b. Plate waste
c. Method of cooking – following recipes, quality varies, and tray delivery,
sitting on the hall long periods
d. Prepared appropriately, i.e. culture preference
e. Portion size, appropriate quantity
f. Temperature appropriate – tray table and on receipt.
g. Color
h. Tray delivery

INTERVIEWING:

1. Alert and oriented residents
2. Families of unresponsive residents
3. Staff members, especially NA's
4. Dietary staff

WHAT TYPE OF QUESTIONS:

1. **RESIDENTS:**

a. How is the food?
b. Do you get enough to eat?
c. Do you like the food here?
d. What is the variety?
e. How does the food look? Taste? Smell?
f. Do you get what you like?
g. If you do not like a particular food, are you offered a substitute?
h. If you ask for a substitute, do you get it? How does staff respond?
i. Are you on a special diet? If yes, are you served foods on your diet?
j. Is the temperature appropriate? Hot food is hot? Cold food is cold?
k. Do they give you the help you need?
l. If you need help opening milk cartons, cutting meat, do you receive assistance?
m. If you need help feeding yourself, do you get assistance?
n. Have you talked to anyone in dietary? (kitchen)
o. What time do they serve meals? Consistent?
p. What time do you get offered snacks? Other snacks?
q. Have you lost weight?
r. Are you getting enough fluids? Offered? Accessible?

2. **FAMILIES*:***

a. Have you seen weight loss since admission?

b. What type of food did the resident enjoy at home?
c. Did the resident eat alone or with family?
d. How often/what size meals did the resident eat?
e. Have you observed how much the resident eats/what the resident likes?
f. Do you feel the resident receives enough assistance?
g. Where does the resident eat (dining room, in room in bed, in wheelchair)?
h. Did the resident snack often? What did the resident snack on?
i. Any dietary restrictions?
j. Food preferences (likes/dislikes/temperature/size)?

3. **STAFF:**

a. How long does it take to feed resident? Does the resident eat well?
b. Does the resident eat better in bed or in chair? (dining room vs. room)
c. What can resident do for him/herself?
d. Do you offer snacks during the day?
e. Do you offer substitutes?
f. Does resident refuse?
g. Does resident exhibit behaviors during eating?
h. Have you asked resident about food (likes/dislikes)?
i. How often do you ask residents about preferences?
j. Is resident appropriate for restorative feeding program?
k. Are meals adjusted for resident's preferences?
l. Do you know of residents with weight loss?
m. What do you do when you see a full tray come back?
n. What adjustment have you made to increase intake?
o. What types of fluids are available between meals?
p. Who is responsible for making them available?
q. What records do you have to follow weight loss?
r. What is your system to get supplements from the kitchen to the residents?
s. Who gets them?
t. How do you know this?
u. Do you know what substitutes are available in the kitchen?
v. Do you tell the resident about them when they dislike what is served?
w. Are you aware of significant weight loss or gain in the resident?
x. If there is a variance what is your process/procedures to intervene? Time of day resident weighed? Medical condition?
y. How much assistance is required for each resident? Where do you get that information?
z. How do you determine how much the resident consumed? What training did you get to prep you for this?
aa. Why do you think this resident is not eating? How long has this been going on?
bb. How do you determine where the resident likes to eat?
cc. How do you identify risk factors for resident malnutrition? What are they for particular residents?
dd. Accuracy of scales?

4. **DIETITIAN:**

a. How do you adjust therapeutic diets to incorporate resident preferences?
b. How often do you speak to the resident about this?
c. What type of interventions are used for weight loss?
5. **KITCHEN STAFF:**
a. What is your system to prepare trays with residents' likes and dislikes in mind?
b. How long does your tray service appliance (metal plate liner, etc.) hold heat?
c. What do you do when a resident's tray comes back untouched?
6. **OMBUDSMAN:**
a. Do you have any concerns regarding food? snacks? weight loss? feeding assistance?
b. Do you have any concerns from your observations of mealtimes?
7. **FOLLOW-UP:**
a. If a problem with weight loss is identified, we would ask to see policy and procedure book.
b. How do staff communicate when weight loss has been identified?
c. What do assessments (oral pain, swallowing, thrush from meds) look like?
d. What types of drug therapies are the residents on?

RECORD REVIEW:
Do after observation of resident.
1. Admission Assessment and Record
a. Age, nationality, height, weight, diagnosis
b. Nurses' notes/ MDS/ nutritional/dietary assessment/ care plan/ RAPS
2. Nutritional Intervention
a. Planned, implemented (supplements, vitamins, double portions)?
3. Physician's Orders
a. Diet order – form, supplements
b. Medications – pharmacy notes
c. Therapies – OT, PT, speech
4. Weights Over Time
a. Calculation % of weight loss (significant?)
b. Weight record/V/S
5. Labs
a. Albumin; H & H; AG ratio; K; magnesium
6. Meal Consumption
a. Supplements; Intake and Output records for tube feeders
7. Skin Assessment
8. Comprehensive Assessment
a. MDS – sections B,E,G,K,L,M,N,O
b. RAPS
c. Care Plan – goals, approaches (restorative, maintenance)
9. Dietary Notes/Section
a Nutritional Assessment
b. Progress Notes
c. Food preferences
10. Social Worker's Notes
a. Dietary habits/patterns

b. Behavior/referrals
c. Family/resident dynamics/education/culture
11. Nurse’s and MD’s Notes
a. Hospital admissions, acute episodes
12. Discharge Summary from the Hospital
13. Miscellaneous
a. MAR
b. Flow sheet - % intake
c. Intake and Output Record
d. Policy/Procedures
e. Nourishment List

SELF SURVEY MODULE
483.25 (j) DEHYDRATION
TAG F327

REGULATION:
F327 Dehydration
(j) Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.
INTENT:
The intent of this regulation is to assure that the resident receives sufficient amount of fluids based on individual needs to prevent dehydration.
OBSERVATIONS
1. Is water at bedside?
a. Is it fresh and clean?
2. What access is there to water?
a. Mobility of resident
b. How close is water?
c. Accessibility to water fountain? Is it clean?
3. Can residents drink from container by themselves, i.e., RDM, dexterity, contractures, cognition?
4. Are assistive devices available?
5 What are resident's non-verbal cues?
6. Are pitchers labeled?
7. Are wanderers and those out of room also offered fluids?
8. What time is water passed?
9. Are liquids on food tray?
a. Amount of fluids on tray?
b. Is set-up provided?
c. Are fluids opened for resident?
d. Are fluids offered by staff before tray is removed?
e. Are fluids being consumed?
1. If not, are substitutes being offered and encouraged and reported?
f. What types of fluids are offered?
g. How does staff respond to full tray at end of meal?
10. During mealtimes are residents allowed enough time to eat and drink?
11. Supervision of residents
a. Eating off each other's trays, etc.?
12. Is there access to bathroom?
13. Are trays returned to kitchen with unopened containers?
a. How much goes back on food cart?
14. Are liquids as ordered, i.e., consistency, amounts, supplements and preferences as indicated on meal card?
15. Are fluids offered between meals and encouraged, especially for room bound residents, i.e., during care?
16. Is free water supplemented?
17. Are supplements and between meal fluids offered so as not to interfere with appetite?

a. Are residents offered water in addition to supplements?

18. **ASSESSMENT OF RESIDENT:**

a. Skin, tugor, dry scaling
b. Dry mouth/tongue, pale mucous membranes, lip smacking
c. Cracked/peeling lips, food caked on teeth/dentures in place
d. Physical limitations:
1. Glasses, hearing aids, splints, restraints/side rails
e. Breath odors
f. Food preferences/textures
g. Weight
1. Appropriate for frame
h. Intake during meals
i. Activity level, dependency
j. Dressings
k. Are residents chewing gum or candy, etc.?
l. Is resident properly positioned during mealtimes?
m. Difficulty swallowing
n. Temperature – are extra fluids offered if weather is warm?
o. Consistency of stools
p. Note color and odor of urine. Is it dark, concentrated? Incontinence? Foley bag?
q. Dentures clean? Ill-fitting?
r. Eyes dull, sunken?
s. Orientation: cognitive status, psychological status, depression
t. Clothing with stains
u. Speech

19. **ENVIRONMENT:**

a. Accommodation for disability, i.e., blindness
b. Room temperature and humidity
c. Check water pitchers
d. Intake and Output signs
e. Tube feedings, IV's, special needs
f. Nourishment refrigerator – residents and personal supplies
1. Refrigerator in nursing station/nourishment room?
g. Is there an ammonia odor in building? Other odors?
h. Accessibility to fluids
i. Call bells

20. **MEDICATION PASS:**

a. Does medication nurse offer extra fluids?
b. Do medications ordered contribute to dehydration?

21. **KITCHEN:**

a. Are fluids at appropriate temperatures?

22. **STAFF:**

a. Do they set up the trays and position resident?
b. Beverage of choice available/adequate amount of beverage
c. Is diet appropriate to order?

d. Water passes – timing
e. Positioning of pitchers
f. Offering of fluids
g. Call light response: appropriate follow-up
h. Are fluids encouraged?
i. Are they providing assistance during meals? Assistive devices?
j. When staff give care or answer lights, do they also offer fluids?
k. Does the staff pass out the snacks?
l. Do they offer substitutes?
m. Do they honor choices?
n. Attitude and approach of staff to residents
1. Do they call residents by name?
2. Do they interact with residents?
3. Does the staff sit when feeding residents and provide socialization for resident?
o. Does staff hurry the resident when eating?
p. During medpass do residents who take their meds with applesauce also get offered water?
q. Are staff passing juices?
r. Are fluids thickened for swallowing /precautions taken for residents?
s. Are staff communicating with RN's regarding residents?

INTERVIEWING:

Residents
Family
Staff: NA
Nurse/Med Nurse
Dietary Staff
Dietary Aide
RD and FSD
Care Plan/MDS Coordinator
Activity Director
Housekeeping
Licensed Staff
Ombudsman
Community Advisory Council
Residents Council

QUESTIONS TO ASK:

RESIDENT:

1. Do you get thirsty?
2. What do you like to drink?
3. Is water/fluid available and accessible (water pitchers)?
4. Is it fresh? How often do they change it?
5. Can you reach your pitcher?
6. Do you need assistance with liquids?
a. Can you pour or open containers for your own drink if you have access?
b. Can you use the liquid container that is given to you or do you need a special

cup or for cup to be held for you?
c. Do you use a straw?
7. Is fluid at the appropriate temperature?
8. Can you get water yourself?
9. Do you get any juices or other drinks?
10. Do you get water from staff?
11. How often do they bring you water?
12. How long does it take for staff to bring water when you ask for it?
13. Do you go to the bathroom often?
14. Do you get supplement fluids?
a. Is it too much, too little?
15. Do you get choices in what you want to drink?
16. What beverages are on your meal trays and how much?
17. Liquids available with bed time snacks?
18. Does staff offer juice and other fluids at other times than mealtimes?

FAMILY:

1. When and how often do you visit?
2. Do you find water in his or her cup?
3. Do you see them offer water to the resident?
4. Does he or she complain of thirst?
5. Is the resident's urine strong smelling, color change, etc.?
6. Do you see them helping with lids or cartons during mealtimes and in between supplements?
7. Is there a filled water pitcher in resident's room when you visit?
a. Is it within reach?
8. Do you feel resident is getting enough to drink?
9. Have you ever noticed dry lips, dry skin, swollen tongue, sunken eyes, skin breakdown?
10. What fluids does your resident like?
11. What did resident enjoy to drink prior to nursing home admittance?

12. Does resident appear thirsty? Do you offer water?
13. Do you think staff offers water when you are not here? If not, why do you believe not?
a. Have you discussed this with staff or addressed in care planning?
b. What was their response or care plan? Is it followed through with?

ROOMMATE AND FAMILY:

1. How often do you observe staff bringing or offering water?
2. How often do they assist in giving fluids?
3. Does your roommate ask for water? Does the resident receive it?

STAFF:

1. How often do you fill pitchers for this resident? (Observe for filled pitchers)
2. Do you work with this resident regularly?
3. Are you familiar with his/her needs?
4. Is this resident on diuretics?
5. Does this resident have special needs, i.e., equipment, physical needs, visual?
6. How do you identify those who need special assistance or devices?

7. Do they complain about not getting enough water?
8. Does this resident need encouragement to drink?
9. Are there swallowing problems? Do you have to use thickening?
10. Has the residence expressed fluid preference?
11. What liquid supplement is resident offered? Frequency?
12. If resident refuses, whom do you tell? What is done?
13. Are there any fluid restrictions for this resident?
14. Have you identified any factors that would put resident at risk for dehydration, i.e., swallowing, chewing, etc.?
15. Do you have any residents that you monitor for Intake and Output? How?
16. Is staff aware of importance of monitoring for adequate fluid intake?
17. Are alternatives offered (popsicles, gelita, etc.)?
18. What are the schedules for providing fluids/water?
19. Do the residents get to choose their drinks?
20. How are residents assisted with their containers?
21. How do you know who is high risk for dehydration?
22. How would a new staff person know who would need special assistance or is at risk?
23. How do you assess a resident's fluid needs?
24. What programs are in place to encourage intake and assist with output (toileting)?
25. Is there an inservice/training on dehydration (if identified)?
26. How often is resident offered water?
27. Does resident need any assistive device or adaptation to accessibility or ability to drink?
28. What methods/strategies do you use to measure fluid intake for residents?
29. Have you assessed the resident's preference for drinking utensil (i.e., cup, mug, plastic, glass)?

NA's:

1. How often do you offer water?
2. Does each resident have a water pitcher/glass?
3. How often do you toilet resident?
4. Do you know which residents need extra fluids? How do you know?
5. Do you notice strong urine odors when changed?

6 How well does the resident take fluids?

DIETARY:

1. Do you keep other beverages on hall?
2. How much fluid is included in meals?
3. How do you calculate each resident's needs?
4. Do you have water with meals?
5. How much water received on trays?

ACTIVITIES:

1. Do you have fluids available during activities?
2. How often (every activity, only parties, only eating related activities)?

FOLLOW-UP:

1. Has this resident been monitored for Intake and Output? (staff, family, resident – if alert and oriented)
2. Has any lab work been done recently? (staff)

3. Any recent infection, illness or fever?
4. Were fluids adjusted during illness?

OMBUDSMAN AND COMMUNITY ADVISORY COUNCIL:

1. Any concerns related to dehydration
2. Any observations related to dehydration
3. Any concerns regarding Community Advisory Committee
4. Do you observe residents thirsty?
5. Have you received complaints from residents and/or families?
6. Is water accessible? Close-by and in proper type cup?
7. Do you observe urine in catheter bags dark/concentrated?
8. Same questions as family

RESIDENT COUNCIL:

1. Questions similar to resident
2. Observations of residents who cannot speak for themselves

RECORD REVIEW

1. MDS

a. Intake and output
b. Vision category
c. Behavioral section – ability to understand and cognition
d. Dehydration section
e. Skin condition, internal bleeding, output exceeds input, constipation, diarrhea, fecal impaction, abnormal labs, ROM limitation, leave 25% or more of meal, continence, UTI's in last 30 days, diuretics, dizziness, vomiting, swallowing problems.

2. Weight checks and change
3. Assistance needed (dependence) with feeding
4. Labs

a. abnormal vs. normal (vitamin deficiency, BUN, sodium, potassium, digixon)

5. Diagnosis
6. Medications

a. diuretics, laxatives, antipsychotic, sedatives, or any that can cause nausea, vomiting and diarrhea
b. Tube feeds

7. Vital sign sheet – elevated temperature and blood pressure level
8. Nurses notes – acute changes and recent hospitalizations
9. Physician orders

a. Fluid restriction or diet (special) and any assistive devices needed
b. Tube feeding and type and orders for fluid needs

10. Social work/notes – family bringing food, fluid and dietary preferences
11. Dietary

a. Usual intake levels, concerns related to fluid level, how plan for fluid restriction with nursing
b. Assessment for fluid needs and check against doctor's orders.
c. Nutritional needs, mode of intake, preferences

12. Care plan issues – at risk and RAPS approaches
13. MARS – to see if omitting medications/resident refusing

14. Intake and Output records
15. Physician and pharmacy/ notes/reviews – blood pressure checks, blood levels
16. Rehab/O.T – fine/gross motor skills and need for special device and recommendations for these needs
17. Speech pathology – swallowing difficulties and special needs to address – thickened fluids
18. ADL's – eating ability
19. Age and diagnosis (diabetes) and gender and physical activity level
20. Admitted with pressure sores – treatment records
21. History and physical – any facts
22. Possibility of falls
23. NA flow sheets (meal intake and elimination, i.e. loose stools, constipation
24. Nursing assessment – upon admission (sunken eyeballs, tongue swollen)
25. Risk factors scale and sheets
26. Care Plan
a. Interventions
27. Dental notes
28. Nurses' notes – acute episodes (edema, dry skin, falls, dizziness), observations
29. Changes (mental and physical)
30. Flow sheets (Intake and Output – note for tube feed and IV administration, vitals, weights)
31. Labs (electros, H and H, BUN, urinalysis, creatine)
32. Social Worker's notes (grievances, FC, Residents Council minutes)
33. History and Physical, discharge summary, ER records, admission records
34. Psychological consults (i.e., behavior diagnosis, mental status)
35. Skin assessments (drains, decubs, surgeries)
36. RAI – did they trigger for any of these problems?
37. Tube feeding – formula; administered as suggested
38. Nutritional records (notes) – water correct; nausea or vomiting
39. Physicians Notes – Intake and Output records; diarrhea or constipation
40. Skin assessments
41. MD orders – NPO or thickened liquids; fluid restrictions; TX dialysis; drugs
42. Progress notes
43. Recurrent UTI's
44. Therapy assessment (SLP)
45. Current diet/supplements, etc. (any thickener)
46. Behavioral records (delirium, etc.)
47. Update Care Plan with changes in hydration
48. Hospital records (ex. Discharge summary/Complaints)

SELF SURVEY MODULE

F329

(Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06)

§483.25(l) Unnecessary Drugs

1. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

(i) In excessive dose (including duplicate therapy); or

(ii) For excessive duration; or

(iii) Without adequate monitoring; or

(iv) Without adequate indications for its use; or

(v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(vi) Any combinations of the reasons above.

2. Antipsychotic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

(i) Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

(ii) Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

INTENT: §483.25(l) Unnecessary drugs

The intent of this requirement is that each resident's entire drug/medication regimen be managed and monitored to achieve the following goals:

• The medication regimen helps promote or maintain the resident's highest practicable mental, physical, and psychosocial well-being, as identified by the resident and/or representative(s) in collaboration with the attending physician and facility staff;

• Each resident receives only those medications, in doses and for the duration clinically indicated to treat the resident's assessed condition(s);

• Non-pharmacological interventions (such as behavioral interventions) are considered and used when indicated, instead of, or in addition to, medication;

• Clinically significant adverse consequences are minimized; and

• The potential contribution of the medication regimen to an unanticipated decline or newly emerging or worsening symptom is recognized and evaluated, and the regimen is modified when appropriate.

NOTE: This guidance applies to all categories of medications including antipsychotic medications.

Although the regulatory language refers to "drugs," the guidance in this document generally will refer to "medications," except in those situations where the term "drug" has become part of an established pharmaceutical term (e.g., adverse drug event, and adverse drug reaction or consequence).

For purposes of this guidance, references to "the pharmacist" mean the facility's licensed pharmacist, whether employed directly by the facility or through arrangement.

The surveyor's review of medication use is not intended to constitute the practice

of medicine. However, surveyors are expected to investigate the basis for decisions and interventions affecting residents.

DEFINITIONS

Definitions are provided to clarify terminology related to medications and to the evaluation and treatment of residents.

• **"**Adverse consequence" is an unpleasant symptom or event that is due to or associated with a medication, such as impairment or decline in an individual's mental or physical condition or functional or psychosocial status. It may include various types of adverse drug reactions and interactions (e.g., medicationmedication, medication-food, and medication-disease).

NOTE: Adverse drug reaction (ADR) is a form of adverse consequences. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term "side effect" is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.

• "Anticholinergic side effect" is an effect of a medication that opposes or inhibits the activity of the parasympathetic (cholinergic) nervous system to the point of causing symptoms such as dry mouth, blurred vision, tachycardia, urinary retention, constipation, confusion, delirium, or hallucinations.

• "Behavioral interventions" are individualized non-pharmacological approaches (including direct care and activities) that are provided as part of a supportive physical and psychosocial environment, and are directed toward preventing, relieving, and/or accommodating a resident's distressed behavior.

• "Clinically significant" refers to effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being either positively by preventing, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

• "Distressed behavior" is behavior that reflects individual discomfort or emotional strain. It may present as crying, apathetic or withdrawn behavior, or as verbal or physical actions such as: pacing, cursing, hitting, kicking, pushing, scratching, tearing things, or grabbing others.

• "Dose" is the total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the daily dose.

o "Excessive dose" means the total amount of any medication (including duplicate therapy) given at one time or over a period of time that is greater than the amount recommended by the manufacturer's label, package insert, current standards of practice for a resident's age and condition, or

clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals and that lacks evidence of:
– A review for the continued necessity of the dose;
– Attempts at, or consideration of the possibility of, tapering a medication; and
– A documented clinical rationale for the benefit of, or necessity for, the dose or for the use of multiple medications from the same pharmacological class.

• "Duplicate therapy" refers to multiple medications of the same pharmacological class/category or any medication therapy that substantially duplicates a particular effect of another medication that the individual is taking.

• "Duration" is the total length of time the medication is being received.

o "Excessive Duration" means the medication is administered beyond the manufacturer's recommended time frames or facility-established stop order policies, beyond the length of time advised by current standards of practice, clinical practice guidelines, clinical studies or evidence-based review articles, and/or without either evidence of additional therapeutic benefit for the resident or clinical evidence that would warrant the continued use of the medication.

• "Extrapyramidal symptoms (EPS)" are neurological side effects that can occur at any time from the first few days of treatment to years later. EPS includes various syndromes such as:

o Akathisia, which refers to a distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing, or rocking.

o Medication-induced Parkinsonism, which refers to a syndrome of Parkinson-like symptoms including tremors, shuffling gait, slowness of movement, expressionless face, drooling, postural unsteadiness and rigidity of muscles in the limbs, neck and trunk.

o Dystonia, which refers to an acute, painful, spastic contraction of muscle groups (commonly the neck, eyes and trunk) that often occurs soon after initiating treatment and is more common in younger individuals.

• "Gradual Dose Reduction (GDR)" is the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued.

• "Indications for use" is the identified, documented clinical rationale for administering a medication that is based upon an assessment of the resident's condition and therapeutic goals and is consistent with manufacturer's recommendations and/or clinical practice guidelines, clinical standards of practice, medication references, clinical studies or evidence-based review articles that are published in medical and/or pharmacy journals.

• "Insomnia" is the inability to sleep characterized by difficulty falling asleep, difficulty staying asleep, early waking, or non-restorative sleep, which may result in impaired physical, social, or cognitive function.

• "Medication Interaction" is the impact of another substance (such as another medication, nutritional supplement including herbal products, food, or substances

used in diagnostic studies) upon a medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

- "Medication Regimen Review" (MRR) is a thorough evaluation of the medication regimen by a pharmacist, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities in collaboration with other members of the interdisciplinary team.[51]
- "Monitoring" is the ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline data in order to:
  - Ascertain the individual's response to treatment and care, including progress or lack of progress toward a therapeutic goal;
  - Detect any complications or adverse consequences of the condition or of the treatments; and
  - Support decisions about modifying, discontinuing, or continuing any interventions.
- "Neuroleptic Malignant Syndrome" (NMS) is a syndrome related to the use of medications, mainly antipsychotics, that typically presents with a sudden onset of diffuse muscle rigidity, high fever, labile blood pressure, tremor, and notable cognitive dysfunction. It is potentially fatal if not treated immediately, including stopping the offending medications.
- "Non-pharmacological interventions" refers to approaches to care that do not involve medications, generally directed towards stabilizing or improving a resident's mental, physical or psychosocial well-being.
- "Psychopharmacological medication" is any medication used for managing behavior, stabilizing mood, or treating psychiatric disorders.
- "Serotonin Syndrome" is a potentially serious clinical condition resulting from overstimulation of serotonin receptors. It is commonly related to the use of multiple serotonin-stimulating medications (e.g., SSRIs, SNRIs, triptans, certain antibiotics). Symptoms may include restlessness, hallucinations, confusion, loss of coordination, fast heart beat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhea.
- "Tardive dyskinesia" refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking, although the trunk or other parts of the body may also be affected.

INVESTIGATIVE PROTOCOL
UNNECESSARY MEDICATIONS - MEDICATION REGIMEN REVIEW

Because they are closely related, the investigations of the requirements for medication regimen review and the review for unnecessary medications have been merged.

Objectives

• To determine whether each resident receives or is provided:

o Only those medications that are clinically indicated in the dose and for the duration to meet his or her assessed needs;

o Non-pharmacological approaches when clinically indicated, in an effort to reduce the need for or the dose of a medication; and

o Gradual dose reduction attempts for antipsychotics (unless clinically contraindicated) and tapering of other medications, when clinically indicated, in an effort to discontinue the use or reduce the dose of the medication.

• To determine if the facility in collaboration with the prescriber:

o Identifies the parameters for monitoring medication(s) or medication combinations (including antipsychotics) that pose a risk for adverse consequences; and for monitoring the effectiveness of medications (including a comparison with therapeutic goals); and

o Recognizes and evaluates the onset or worsening of signs or symptoms, or a change in condition to determine whether these potentially may be related to the medication regimen; and follows-up as necessary upon identifying adverse consequences.

• To determine if the pharmacist:

o Performed the monthly medication regimen review, and identified any existing irregularities regarding indications for use, dose, duration, and the potential for, or the existence of adverse consequences or other irregularities; and

o Reported any identified irregularities to the attending physician and director of nursing.

• To determine whether the facility and/or practitioner acted on the report of any irregularity.

Use

Use this protocol during every initial and standard survey. In addition, this protocol may be used on revisits or abbreviated survey (complaint investigation) as necessary.

NOTE: This review is not intended to direct medication therapy. However, surveyors are expected to review factors related to the implementation, use, and monitoring of medications.

The surveyor is not expected to prove that an adverse consequence was directly caused by a medication or combination of medications, but rather that there was a failure in the care process related to considering and acting upon such possibilities.

If during the course of this review, the surveyor needs to contact the attending physician regarding questions related to the medication regimen, it is recommended that the facility's staff have the opportunity to provide the necessary information about the resident and the concerns to the physician for his/her review prior to responding to the surveyor's inquiries.

Procedures

Review the medications (prescription, over-the-counter medications, and nutritional

supplements such as herbal products) currently ordered and/or discontinued by the prescriber at least back to the most recent signed recapitulation/reorder of all medications. Obtain a copy of the current orders if necessary. Gather information regarding the resident's mental, physical, functional, and psychosocial status and the medication-related therapeutic goals identified in the care plan as the basis for further review.

1. Observation and Record Review

Use the table below to guide observations, record review, and interviews with the resident or representative and relevant staff. Observe whether the medication-related interventions are consistently implemented over time and across various shifts. Note deviations from the care plan as well as potential medication-related adverse consequences. Verify observations by gathering additional information; for example, additional record reviews and/or interviews with the resident or representative, relevant staff, and practitioners.

SYMPTOMS, SIGNS, AND CONDITIONS THAT MAY BE ASSOCIATED WITH MEDICATIONS	REVIEW FOR HOW FACILITY MANAGED MEDICATIONS FOR THE RESIDENT
Determine if the resident has been transferred to acute care since the last survey and/or has recently (e.g., the previous 3 months) experienced a change in condition or currently has signs and symptoms, such as: • Anorexia and/or unplanned weight loss, or weight gain • Behavioral changes, unusual behavior patterns (including increased distressed behavior) • Bleeding or bruising, spontaneous or unexplained • Bowel dysfunction including diarrhea, constipation and impaction • Dehydration, fluid/electrolyte imbalance • Depression, mood disturbance • Dysphagia, swallowing difficulty • Falls, dizziness, or evidence of impaired coordination • Gastrointestinal bleeding	Review the record (including the care

• Headaches, muscle pain, generalized or nonspecific aching or pain
• Mental status changes, (e.g., new or worsening confusion, new cognitive decline, worsening of dementia (including delirium))
• Rash, pruritus
• Respiratory difficulty or changes
• Sedation (excessive), insomnia, or sleep disturbance
• Seizure activity
• Urinary retention or incontinence

If observations or record review indicate symptoms or changes in condition that may be related to medications (refer to Tables I and II, supplemented with current medication references), determine whether the facility considered medications as a potential cause of the change or symptom.

plan, comprehensive assessment, and other parts of the record as appropriate) to determine whether it reflects the following elements related to medication management for the resident:

• Clinical indications for use of the medication
• Consideration of nonpharmacological interventions
• Dose, including excessive dose and duplicate therapy
• Duration, including excessive duration
• Consideration of potential for tapering/GDR or rationale for clinical contraindication
• Monitoring for and reporting of:
  o Response to medications and progress toward therapeutic goals
  o Emergence of medication-related adverse consequences
• Adverse consequences, if present and potentially medication-related, note if there

was:
- Recognition, evaluation, reporting, and management by the facility
- Physician action regarding potential medication-related adverse consequences

2. Interview

Interview the resident and or family/responsible party, to the extent possible, to determine:

• His/her participation in care planning and decision making, including discussions of the goals related to the use of medications;
• Whether approaches other than medications (as indicated) were discussed; and
• His/her evaluation of the results of the medication therapy and other approaches (such as decreasing symptoms of pain, improving functional ability).

If during the review, you identify concerns about the lack of indication for use; the dose or duration of a medication; lack of monitoring; failure to implement the care plan; or condition changes or functional decline that may be related to the medication regimen, interview knowledgeable staff to determine:

• Whether the resident has experienced any changes in the functioning or amount of activity that he/she is able to do;
• The clinical rationale for the use of the medication, dose or duration and how the interdisciplinary team is monitoring the resident's response to the medication;
• What process is in place to assure the care plan interventions for medication use are being implemented;
• Whether they were aware that the signs and symptoms may be adverse consequences related to the medication regimen;
• Whether the staff had contacted the attending physician to discuss the signs and symptoms and the current medication regimen;
• Whether and how the physician responded when informed of suspected adverse medication consequences; and
• Whether the pharmacist performed a medication regimen review and identified related signs and symptoms, or the staff informed the pharmacist of them if they occurred after the last pharmacist visit.

Interview the physician, as appropriate, to determine:

• Whether staff notified him/her of potential medication-related issues and concerns;
• His/her assessment of the significance of medication-related issues and concerns; and
• Rationale for his/her management of the resident's medications and/or medication-related issues or concerns.

3. Medication Regimen Review (MRR)

Review for compliance with the MRR requirements at F428. Determine:

• If the pharmacist had identified and reported to the director of nursing and attending physician any irregularities with the medication regimen such as:

o The emergence or existence of clinically significant adverse consequences;

o Excess dose or duration, lack of monitoring, lack of indication for use, lack of GDR (as indicated) or behavioral interventions for residents receiving antipsychotics, medication interactions potentially affecting the medication's effectiveness; and

• Whether the attending physician and the director of nursing acted on any irregularities identified in the report. The responses from the attending physician could include the following:

o Changed the medication regimen in response to the concern raised in the report (or after additional review of the situation);

o Provided a clinically pertinent rationale that is relevant to that specific resident's signs and symptoms, prognosis, test results, etc., documenting or indicating why the benefit of the medication(s) or dose(s) outweighed the risks of the adverse consequence;

o Provided a clinically pertinent rationale for why any gradual dose reduction (for antipsychotic medications) and/or tapering (for other medications) is contraindicated, even for a trial period; or

o Provided a clinically pertinent rationale for why a particular medication, dose, or duration is appropriate for a resident despite its risks (for example, the resident has had recurrent seizures unless he/she receives anticonvulsant dosing that exceeds the usual recommended serum medication concentration level or therapeutic range, and the attending physician and facility have been monitoring for and addressing adverse consequences).

• If the pharmacist identified a suspected adverse consequence, and the attending physician did not respond, determine if staff followed up with the attending physician.

NOTE: If the staff and pharmacist identify a medication that they believe may be causing a serious adverse consequence or a risk of clinically significant adverse consequences for the resident, and the attending physician did not address the risks or harm to the resident, determine what steps staff took; e.g., contacting the medical director to review the situation and address the issue with the attending physician, as necessary. See guidance at 42 CFR 483.75(i) Medical Director (F501) for additional guidance.

If problems are identified with the MRR, interview the pharmacist, as indicated, to determine:

• How he/she conducts the MRR, including the frequency and extent of the medication review and under what circumstances a review might be conducted more often than monthly;

• How the facility communicates with him/her regarding medication-related

issues in specific residents; and
• How he/she approaches the MRR process for short stay residents.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of Regulation (F329)

The unnecessary medication requirement has six aspects in order to assure that medication therapy is appropriate for the individual resident. The facility must assure that medication therapy (including antipsychotic agents) is based upon:
• An adequate indication for use;
• Use of the appropriate dose;
• Provision of behavioral interventions and gradual dose reduction for individuals receiving antipsychotics (unless clinically contraindicated) in an effort to reduce or discontinue the medication;
• Use for the appropriate duration;
• Adequate monitoring to determine whether therapeutic goals are being met and to detect the emergence or presence of adverse consequences; and
• Reduction of dose or discontinuation of the medication in the presence of adverse consequences, as indicated.

Criteria for Compliance

Compliance with 42 CFR 483.25(l), F329, Unnecessary Medications
For a resident who has been, or is, receiving medication(s), the facility is in compliance if they, in collaboration with the prescriber:
• Assessed the resident to ascertain, to the extent possible, the causes of the condition or symptoms requiring treatment, including recognizing, evaluating, and determining whether the condition or symptoms may have reflected an adverse medication consequence;
• Based on the assessment, determined that medication therapy was indicated and identified the therapeutic goals for the medication;
• Utilized only those medications in appropriate doses for the appropriate duration, which are clinically necessary to treat the resident's assessed condition(s);
• Implemented a gradual dose reduction and behavioral interventions for each resident receiving antipsychotic medications unless clinically contraindicated;
• Monitored the resident for progress towards the therapeutic goal(s) and for the emergence or presence of adverse consequences, as indicated by the resident's condition and the medication(s); and
• Adjusted or discontinued the dose of a medication in response to adverse consequences, unless clinically contraindicated.
If not, cite F329.

Noncompliance for F329

After completing the investigation, determine whether or not compliance with the regulation exists. Noncompliance for F329 may include:
• **Inadequate Indications for Use** – Examples of noncompliance related to a medication being used without adequate indications include, but are not limited to:
o Failure to document a clinical reason or demonstrate a clinically pertinent rationale, verbally or in writing, for using medication(s) for a specific resident.

- Prescribing or administering a medication despite an allergy to that medication, or without clarifying whether a true allergy existed as opposed to other reactions (e.g., idiosyncratic reaction or other side effect).
- Failure to provide a clear clinical rationale for continuing a medication that may be causing an adverse consequence.
- Initiation of an antipsychotic medication to manage distressed behavior without considering a possible underlying medical cause (e.g., UTI, congestive heart failure)or environmental or psychosocial stressor.
- Initiation of a medication presenting clinically significant risks without considering relative risks and benefits or potentially lower risk medications.
- Concomitant use of two or more medications in the same pharmacological class without a clinically pertinent explanation.

• **Inadequate Monitoring** – Examples of noncompliance related to inadequate monitoring include, but are not limited to:

- Failure to monitor the responses to or effects of a medication and failure to respond when monitoring indicates a lack of progress toward the therapeutic goal (e.g., relief of pain or normalization of thyroid function) or the emergence of an adverse consequence.
- Failure to monitor a medication consistent with the current standard of practice or manufacturer's guidelines.
- Failure to carry out the monitoring that was ordered or failure to monitor for potential clinically significant adverse consequences. For example, use of warfarin in conjunction with:

– Inadequate or absent monitoring of PT/INR during treatment; and/or

– Failure to recognize and monitor the increased risk of adverse consequences when the resident is receiving other medications that are known to increase the risk of bleeding or to interact with warfarin and increase PT/INR.

Excessive Dose (including duplicate therapy) – Examples of noncompliance related to excessive dose include, but are not limited to:

- Giving a total amount of any medication at one time or over a period of time that exceeds the amount recommended by the manufacturer's recommendations, clinical practice guidelines, evidence-based studies from medical/pharmacy journals, or standards of practice for a resident's age and condition, without a documented clinically pertinent rationale.
- Failure to consider periodically the continued necessity of the dose or the possibility of tapering a medication.
- Failure to provide and/or document a clinical rationale for using multiple medications from the same pharmacological class.

• **Excessive Duration** – Examples of noncompliance related to excessive duration include, but are not limited to:

- Continuation beyond the manufacturer's recommended time frames, the stop date or duration indicated on the medication order, facilityestablished

stop order policies, or clinical practice guidelines, evidencebased studies from medical/pharmacy journals, or current standards of practice, without documented clinical justification.

- Continuation of a medication after the desired therapeutic goal has been achieved without evaluating whether the medication can offer any additional benefit, for example:

– Use of an antibiotic beyond the recommended clinical guidelines or the facility policy without adequate reassessment of the resident and determination of continuing need.

– Failure to re-evaluate the rationale for continuing antipsychotic medication initiated in an emergency after the acute phase has stabilized.

• **Adverse Consequences** – Examples of noncompliance related to adverse consequences include, but are not limited to:

- Failure to act upon (i.e., discontinue a medication or reduce the dose or provide clinical justification for why the benefit outweighs the adverse consequences) a report of the risk for or presence of clinically significant adverse consequence(s);
- Failure to respond to actual or potentially clinically significant adverse consequences related to the use of warfarin when the PT/INR exceeds the target goal.

• **Antipsychotic Medications without Gradual Dose Reduction and Behavioral Interventions unless Clinically Contraindicated** – Examples of noncompliance related to this requirement include, but are not limited to:

- Failure to attempt GDR in the absence of identified and documented clinical contraindications.
- Prolonged or indefinite antipsychotic use without attempting gradual dose reductions.
- Failure to implement behavioral interventions to enable attempts to reduce or discontinue an antipsychotic medication.

Potential Tags for Additional Investigation

If noncompliance with 483.25(l) has been identified, then concerns with additional requirements may also have been identified. The surveyor is cautioned to investigate these related additional requirements before determining whether noncompliance with the additional requirements may be present. Examples of some of the related requirements that may be considered when noncompliance has been identified include the following:

• 42 CFR 483.10(b)(11), F157, Notification of Changes

- Review whether the facility contacted the attending physician regarding a significant change in the resident's condition in relation to a potential adverse consequence of a medication, or if the resident has not responded to medication therapy as anticipated and/or indicated.

• 42 CFR 483.10 (b)(3) and (4), F154, F155, Notice of Rights and Services and (d)(2) Free Choice

- Determine whether the resident was advised of her/his medical condition and therapy and was informed about her/his treatment including

medications and the right to refuse treatments.
• 42 CFR 483.20(b), F272, Comprehensive Assessments
o Review whether the facility's initial and periodic comprehensive assessments include an assessment of the resident's medication regimen.
• 42 CFR 483.20(k)(1) and (2), F279, F280, Comprehensive Care Plans
o Review whether the resident's comprehensive care plan: a) was based on the assessment of the resident's conditions, risks, needs, and behavior; b) was consistent with the resident's therapeutic goals; (c) considered the need to monitor for effectiveness based on those therapeutic goals and for the emergence or presence of adverse consequences; and (d) was revised as needed to address medication-related issues.
• 42 CFR 483.25(a)(1), F310, Decline in ADL
o Review whether the facility had identified, evaluated, and responded to a new or rapidly progressive decline in function, development or worsening of movement disorders, increased fatigue and activity intolerance that affected the resident's ADL ability in relation to potential medication adverse consequences.
• 42 CFR 483.25(d), F315, Urinary Incontinence
o Review whether the facility had identified, evaluated, and responded to a change in urinary function or continence status in relation to potential medication adverse consequences.
• 42 CFR 483.25(f)(1)&(2), F319, F320, Mental and Psychosocial Functioning
o Review whether the facility had identified, evaluated, and responded to a change in behavior and/or psychosocial changes, including depression or other mood disturbance, distress, restlessness, increasing confusion, or delirium in relation to potential medication adverse consequences.
• 42 CFR 483.25(i)(1), F325, Nutritional Parameters
o Review if the facility had identified, evaluated, and responded to a change in nutritional parameters, anorexia or unplanned weight loss, dysphagia, and/or swallowing disorders in relation to potential medication adverse consequences.
• 42 CFR 483.25(j), F327, Hydration
o Review if the facility had identified, evaluated, and responded to a change in hydration or fluid or electrolyte balance (for example, high or low sodium or potassium) in relation to potential medication adverse consequences.
• 42 CFR 483.40(a), F385, Physician Supervision
o Review if the attending physician supervised the resident's medical treatment, including assessing the resident's condition and medications, identifying the clinical rationale, and monitoring for and addressing adverse consequences.
• 42 CFR 483.40(b), F386, Physician Visits
o Review if the attending physician or designee reviewed the resident's total program of care and wrote, signed, and dated progress notes covering pertinent aspects of the medication regimen and related issues.
• 42 CFR 483.60(c), F428, Medication Regimen Review

- Review whether the licensed pharmacist has provided consultation regarding the integrity of medication-related records (e.g., MAR, physician order sheets, telephone orders), and potential or actual medication irregularities.

• 42 CFR 483.75(i), F501, Medical Director

- Review whether the medical director, when requested by the facility, interacted with the attending physician regarding a failure to respond or an inadequate response to identified or reported potential medication irregularities and adverse consequences; and whether the medical director collaborated with the facility to help develop, implement, and evaluate policies and procedures for the safe and effective use of medications in the care of residents.

IV. DEFICIENCY CATEGORIZATION (Part IV, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirement, and identified any deficient practice(s) that demonstrate that noncompliance with the regulation at F329 exists, the team must determine the severity of each deficiency, based on the resultant harm or potential for harm to the resident.

The key elements for severity determination for F329 are as follows:

1. Presence of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Examples of actual or potential harm/negative outcomes for F329 may include, but are not limited to:

• Potential for life-threatening toxicity from excessive dose or lack of indication for the use of digoxin.

• Complications (such as diarrhea with life threatening fluid loss, nephrotoxicity, hearing loss, or anaphylactic shock) from use of an antibiotic when no clear indication for use has been established or response to the use has not been monitored.

• Fractures or falls with injury resulting from the continuing use of medications (e.g., hypnotics/sedatives, antipsychotics, antidepressants, antihypertensives) in the presence of predisposing risks or adverse consequences such as persistent dizziness or recurrent falling without intervening or reevaluating the need for and dose of the medication believed to be the cause of the gait instability.

2. Degree of potential or actual harm/negative outcome(s) due to a failure related to unnecessary medications.

Identify how the facility practices caused, resulted in, allowed, or contributed to the actual or potential for harm:

• If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; or

• If harm has not yet occurred, determine how likely is the potential for serious injury, impairment, death, compromise, or discomfort to occur to the resident.

3. The immediacy of correction required.

Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F329. First, the team must rule out whether Severity Level 4,

Immediate Jeopardy to a resident's health or safety, exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q.)

NOTE: The death or transfer of a resident who was harmed or injured as a result of facility noncompliance does not remove a finding of immediate jeopardy. The facility is required to implement specific actions to remove the jeopardy and correct the noncompliance which allowed or caused the immediate jeopardy.

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

• Has allowed, caused, or resulted in, or is likely to allow, cause, or result in serious injury, harm, impairment, or death to a resident; and

• Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples may include, but are not limited to:

• Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.

• Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice and to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.

• Failure to recognize developing serotonin syndrome (e.g., confusion, motor restlessness, tremor) in a resident receiving a SSRI, leading to the addition of medications with additive serotonin effect or medication to suppress the symptoms.

• Failure to recognize and respond to signs and symptoms of neuroleptic malignant syndrome (NMS).

• In the presence of gastrointestinal bleeding, the failure to recognize medication therapies (such as NSAIDs or COX-2 inhibitors, bisphosphonates) as potentially causing or contributing to the gastrointestinal bleed, resulting in the continued administration of the medication, until the resident required hospitalization for severe bleeding.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is Not Immediate Jeopardy

Level 3 indicates noncompliance that resulted in actual harm, and may include, but is not limited to, clinical compromise, decline, or the resident's inability to maintain and/or reach his/her highest practicable well-being. Examples may include, but are not limited to:

• Facility failure to take appropriate action (e.g., suspending administration of the anticoagulant) in response to an INR greater than 4 and less than 9 for a resident who is receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.

• Facility failure to evaluate the medication regimen as a potential cause of seizure activity resulting in the addition of anticonvulsants to treat recent-onset seizures that can be adverse consequences of medications.
• Facility failure to implement a GDR that was not contraindicated in a resident receiving prolonged, continuous antipsychotic therapy resulting in functional decline, somnolence, lethargy, tremors, increased falling, or impaired ambulation.
NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Severity Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that resulted in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well-being. The potential exists for greater harm to occur if interventions are not provided. Examples may include, but are not limited to:
• Facility failure to take appropriate action (e.g., change or suspend administration of the warfarin dose) for a resident who has an INR greater than 4 and less than 9 without any bleeding.
• Failure to monitor INR for a resident who has been stabilized on warfarin, but who has not had bleeding.
• Facility failure to identify and act upon minor symptoms of allergic response to medications, such as a rash.
• Facility failure to monitor for response to therapy or for the emergence or presence of adverse consequences before the resident has experienced an adverse consequence or decline in function (e.g., monitoring periodically for symptoms of behavioral distress in someone receiving psychopharmacological medication; monitoring thyroid function at least annually in an individual receiving thyroid hormone replacement; and monitoring hydration status and basic metabolic profile for a resident receiving diuretics or ACE inhibitors, who had a change in mental status after the onset of diarrhea).

Severity Level 1: No Actual Harm with Potential for Minimal Harm

The failure of the facility to provide appropriate care and services to manage the resident's medication regimen to avoid unnecessary medications and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

SELF SURVEY MODULE
483.35 DIETARY SERVICES
TAG F364

REGULATION:
F364 (d) Food
Each resident receives and the facility provides--
(1) Food is prepared by methods that conserve nutritive value, flavor and appearance;
(2) Food that is palatable, attractive and at the proper temperature.

INTENT:
The intent of this regulation is to assure that the nutritive value of food is not compromised and destroyed because of prolonged food storage, light and air exposure; prolonged cooking of foods in a large volume of water, prolonged holding on a steamtable and the addition of baking soda. Food should be palatable, attractive and at the proper temperature as determined by the type of food to ensure residents' satisfaction. Refer to 483.15 (c) and/or 483.15 (a).

DATA COLLECTION:

OBSERVATIONS:
1. Purchasing and Receiving
    a. Are the products rotated for freshness?
    b. Are storage refrigerators and freezer temperatures monitored and documented daily?

2. Production Equipment
    a. Is there adequate production equipment for the type and style of the menu?
    b. Is the equipment clean and in good repair?

3. Smallwares
    a. Are there adequate smallwares and portioning utensils?
    b. Are they clean and in good condition?
    c. Are they stored appropriately?
    d. Are food thermometers available?
    e. Have they been calibrated recently?

4. Kitchen Facilities
    a. Is the kitchen clean and in good repair?

5. Meal Preparation
    a. Are foods properly prepared and seasoned per the recipe?
    b. Are meats tender and moist and an appropriate color?
    c. Are vegetables tender, retain color, texture, properly drained and free of excess grease?

d. If cooked leftovers were used, were they dated when stored and used within appropriate time frames? Were they heated to a minimum of 160F?
e. Are foods prepared too far ahead of service causing loss of palatability and nutritional content?
f. Is food appearance attractive?
g. Are food temperature checks completed at each meal service and documented?
h. Are plate warmers, the steamtable and infrared warmers preheated?
i. What time was the food put into holding units prior to service?
j. Are cold foods maintained at cold temperatures during service?
k. Is trayline quick and organized / are portion controls in place?
l. Do meals leave the kitchen in a timely fashion?
m. If food is transported, is the equipment adequate to maintain temperatures?
n. Was the equipment preheated or cooled?
o. Is food merchandising and plate garnishing in place?
p. Are normal accompaniments available with food items e.g. lemon and tartar sauce with fish?
q. Is there a monitoring procedure in place to identify, prevent and correct problems e.g. test trays?

6. Staff Development
    a. Are staff appropriately uniformed?
    b. Are staff using good sanitary practices?
    c. Daily production staff meetings?
    d. Management visibility in service areas?

7. Dining Area (objective evaluations)
    a. Interview residents who have complained about the taste or temperature of food.
    b. Note the length of time it takes for food to get delivered to residents.
    c. Are pureed foods at the consistency as ordered on the diet order?
    d. Request a test tray to go to the affected area or to the unit which is the greatest distance from the kitchen. Check food temperatures and palatability of the test tray at about the time the last resident on the unit is served and begins eating. Do they meet minimum standards?
    e. Do staff offer to reheat food if the temperature is not suitable for the resident?
    f. Is adequate time spent with each resident who needs assistance?

DOCUMENTATION:

1. Menus, recipes and production sheets
    a. Are cycle menus in place?
    b. Is a recipe file available and used?
    c. Are weekly recipe books set up based on the menu cycle for ease of use?
    d. Are food production worksheets used?
    e. Are all documents appropriately approved i.e., menus and extensions are approved by a Registered Dietitian?

2. Purchasing/Receiving
    a. Are food quality standards of the facility specified?
    b. Are approved vendors used?
    c. Are there an adequate number of deliveries made per week?

3. Staff Development
    a. Are the following procedures in place -- orientation, ongoing staff training, outside skills training?
    b. Are regular formal, written departmental audits completed by in-house management staff?

4. MDS, Nutritional Status RAP, Care Plan, Nutrition Notes and Resident Council Minutes
    a. Has the resident lost weight?
    b. Does the resident complain about the taste of many foods?
    c. Does the resident leave 25% or more of food uneaten at most meals?
    d. What kind of diet is the resident receiving?
    e. Does the resident have drug induced anorexia?
    f. What does the care plan say regarding food?
    g. What do nutrition notes say regarding achieving resident goals and food satisfaction?
    h. Do Resident Council Minutes address food complaints? If so, what is the facility response?
    i. If there is a nutritional problem, what does the nutritional status Resident Assessment Protocol say?
    j. Has the resident or a family member filed a grievance concerning food? If so, what is the facility response?
    k. Has a resident satisfaction survey been taken and if so, what are the results?

INTERVIEWS:

RESIDENT INTERVIEWS:

1. Tell me about the food here.
2. Is the hot food hot and the cold food cold?
3. Do you have any diet restrictions?
4. How does your food taste?
5. Are staff checking back with you for satisfaction or correction after your entree is served?
6. Is your food served at a temperature that you like?
7. If no, will staff reheat the food or make a substitution?
8. Is any particular meal a problem?
9. Has the resident notified a staff member of any problems? What does the resident say was the staff member's response?

GROUP INTERVIEW:

1. Is the hot food hot and the cold food cold?
2. Are the meats tender, moist and an appropriate color?
3. Are the meals generally on time or late?
4. If you had a concern about the food, did you tell the staff? What was their response?

NURSING STAFF INTERVIEW:

1. How do you get feedback about a resident's food satisfaction?
2. How do you address residents' complaints regarding food?
3. What do you do if a resident has a complaint about the meal taste or flavor?
4. What do you do if the resident has a complaint about the food temperature or appearance?
5. If the resident is not consuming portions of their food, is nursing staff aware and what are they doing about it?

DINING STAFF INTERVIEW

1. How do you monitor the quality of food at resident receipt?
2. What have been the results of your food monitoring?
3. Have there been any food complaints from the Resident Council?
4. What is being done about those complaints?
5. What do you do when a resident has a complaint about the food?

SELF SURVEY MODULE
483.35 DIETARY SERVICES
TAG F371

REGULATION:
F371 (h) Sanitary Conditions.
The facility must --
(2) store, prepare, distribute, and serve food under sanitary conditions;

INTENT:
The intent of this regulation is to prevent food borne illness and reduce those practices which result in food contamination and compromised food safety to all residents, especially those at high risk.

DATA COLLECTION:

OBSERVATIONS:
A. Food Storage Observations
1. Dry storage
    a. All items are covered, labeled and dated
    b. Bulk foods stored in covered container with identifying name
    c. Cleaning chemicals are stored separately
    d. An effective pest control program that assures the storage area is free from insects and rodents
    e. Storage room is clean (walls, floors, ceilings, shelves, vents and doors)

2. Refrigerator/freezer
    a. Look at temperature controls
    b. Refrigerator - at or below 41 degrees
    c. Freezer - at 0 degrees or below (Thermometers must be visible)
    d. Are refrigerated foods covered, dated, labeled, and shelved to allow air circulation (off the floor)?
    e. Are raw food items stored below cooked items?
    f. Are foods covered, dated and rotated with oldest date to the front?
    g. Cleanliness, free from spills, free of particles or debris on shelves or floors, fans free from dust.

B. Food Preparation Observations
1. Observe for adequate temperature of product when raw shell eggs are being cracked and added to items to be cooked.
2. Are frozen raw meats and poultry thawed in the refrigerator or in cold, running water? Are cooked foods cooled down safely?
3. Observe the temperature (sanitized thermometer) of cooked foods that have been cooled prior to their use.

4. Use proper procedures for storing leftovers, including refrigeration in an appropriate container that is labeled and dated.
5. Multi-step food preparation items that are potentially hazardous (e.g. meat salads, egg salads, casseroles or products containing milk, eggs or mayonnaise) should use proper procedures to prevent cross contamination and food borne illnesses.
6. Observe for proper hand washing and glove use.

C. Food Service Sanitation Observations

1. Are hot foods maintained at 140 degrees F or above and cold food maintained at 41 degrees F or below when served from ?
2. Are food trays, dinnerware, and utensils clean, dry and in good condition (dishes and trays checked for cracks, chips and food debris)?
3. Are pots, pans, utensils and equipment clean, free from rust, bent, cracked or pitted?
4. Are the foods covered until served (including the steam table)?
5. Is food protected from contamination during transportation and distribution?
6. Are employees thoroughly washing hands before and after handling food?
7. Are employees wearing clean, appropriate uniforms and hair coverings?
8. Are towel and soap dispensers readily available?
9. Are utensils clean -- free from grease, food particles?
10. No eating, gum chewing or use of tobacco products while preparing food.
11. Infection control practices are followed to include: staff with communicable diseases or infected skin lesions are not to work with food preparation.
12. Are food preparation equipment, dishes and utensils effectively sanitized to destroy potential food borne illness?
13. Is dishwasher's hot water 140 degrees F and rinse cycle 180 degrees or is chemical sanitation per manufacturer's instructions followed?
14. Is facility following correct manual dishwashing procedures, i.e. three compartment sink, correct water temperature, chemical concentration, and immersion time?
15. Are all items air dried?
16. Assure correct portion sizes are served.
17. Are food contact surfaces and utensils properly sanitized? (cutting boards, knives, blenders, mixers, food processors)

DOCUMENTATION:

D. Food Storage Documentation

1. Refrigerator/freezer temperature log

E. Food Preparation Documentation

1. Follow standard recipes
2. Assure that facility sanitation policy and procedures are followed

F. Food Service Sanitation Documentation

1. Food temperatures from the serving line are recorded on a log.
2. Dish machine temperatures are recorded on a log.
3. Policy and procedures for proper dishwashing techniques using manual and automated systems

INTERVIEWS:

STAFF INTERVIEWS:

G. Food Storage Staff Interviews

1. What are the acceptable temperatures of refrigerators and freezers?
2. Who is responsible for checking the temperatures?
3. How often are the temperatures checked?

SELF SURVEY MODULE
Tag 498

REGULATION:
F 498: Proficiency of Nurse aides.: The facility must ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care.

INTENT:
The intent of this regulation is to determine if "competency in skills and techniques necessary to care for residents' needs" includes competencies in areas such as communication and personal skills, basic nursing skills, personal care skills, mental health and social service needs, basic restorative services and residents rights.

DATA COLLECTION

OBSERVATIONS:
During the resident review observe nurse aides. If problems are identified with a particular staff person, continue to observe that person's performance to determine if it is a one time problem or skill/knowledge base missing.

If there is a specific complaint, a concern or an identified problem with the aides competency then the specific aide, performing this specific task should be observed.

Observe other aides to determine if the issue is specific to one aide, or are aides as a rule deficient in this area.

Observe:

1. Staff transfers (follows care plan, uses safety belts and straps, uses and secures on lifts; positions for pivots)
2. Incontinence care (front to back technique; wash with soap, rinse, dry)
3. Assistance/supervision during resident care activities (during toileting; bathing, dressing, feeding).
4. Handling resident to resident conflict (assistance to room, redirection)
5. Response to resistance to care (talks softly, returns at later time, seeks assistance)
6. Supervision of residents with elopement potential or intrusive wandering..
7. Do nurse aides show competency in skills necessary to: maintain or improve the resident's independent functioning.
8. Do aides carry out appropriate infection control precautions and safety procedures?
9 Do aides follow instructions?

Documentation:

Review nurse aide skills checklists.

Review inservice records. When were staff last inserviced on the skill in question?

Review the facility's policy and procedure for implementing the skill.

Review specific aides files as necessary to determine if the aide has ever had a finding on the registry.

If the facility has a nurse aide training program in house then review the course content of how aides are evaluated on skills.

Interview:

Nurse Aide Interview:

1. How long have you been a nurse aide?
2. Where did you receive your training? and how long it was?
3. What types of inservice education have you attended here in the facility since you were hired as an aide?
4. How do you know what type of care/assistance this resident needs?
5. How are you notified if care changes for the resident?
6. Do you participate in the care planning process for this resident?
7. Has the facility ever provided you with inservice education on (whatever care problem is identified).
8. What is your schedule like? Do you do many back to back schedules?
9. If you need help how do you get it?
10. How are nurse aide assignments made?

Licensed/Registered Staff Interview: Preferably with the Staff Development Coordinator

1. How long has the aide worked in the facility?
2. Who does the check off list on competencies for the aide?
3. How often do you review the performance of the aide?
4. How are training needs identified for nurse aides?
5. If an aide is identified with problems in an area what steps are taken to correct the problem? Are staff re-inserviced? How is the aide monitored to assure that they are now proficient in this area or continuing to be proficient??
6. How has inservice education addressed quality of care problems?
7. Is the aide currently receiving training on a state approved nurse aide training program? If not is the aide under the supervision of a licensed nurse?
8. How is the aide supervised?

9. How are nurse aide requests for assistance handled?
10. How are nurse aide's assignments made?

Resident Interviews

1. Do you know your nurse aide?
2. Does the nurse aide understand how to (ask whatever the issue is, ie turn you, bathe you, etc).
3. Do you have the same aides consistently?
4. Does the nurse aide listen to you if you object, or request that something be done differently?
5. Does the nurse aide respect your rights? Choices? Dignity?

Family Interviews

1. Do you know the nurse aide that takes care of your family member?
2. Does the facility use agency aides?
3. Do the aides seem to know what your family member requires?
4. Have you ever complained about the care your family member received from an aide? What was the facilities response?